D7 Foaming Hand Sanitizer

- Alcohol Free alternative to Triclosan
- NSF E3 approved for Food

Overview

D7 Foaming Hand Sanitizer is based on the active ingredient Benzalkonium Chloride in a unique non-drying, moisturizing and conditioning formulation. D7 Foaming Hand Sanitizer kills 99.9-99.9999% of most common germs that may cause illness in just 15 seconds and is NSF Approved E3 for no-rinse hand sanitizing for food handlers.

Benzalkonium Chloride is listed in the Antiseptic monograph as Category III for safety and efficacy. This category allows Benzalkonium chloride based products to be marketed in use patterns that fall within the monograph as long as the formulations are manufactured under Good Manufacturing Practices (GMP's) and conform to the percentage range in the monograph of 0.1-0.13% for Benzalkonium chloride. Benzalkonium chloride based "leave-on" products meeting the above requirements qualify for use based on monograph prior marketing "grandfathering" with a demonstrated use pattern established for a material time and extent prior to December, 1975.

Typical Properties

	D7 Foaming Hand Sanitizer
Physical form	Light amber liquid
Benzalkonium chloride, active %	0.1
Assay (Epton), meq/kg	6.1-7.1
pH	4.5-6.5
Specific Gravity @25°C	1.00±0.02
Flash point (Setaflash CC)	>200°F(>93°C)

Handling Information

Note - Manufacturing, Packaging and Marketing of this product is subject to regulation by the Food and Drug Administration and may be subject to Enforcement Action. Contact Decon7 Systems LLC for details.
Refer to and follow the guidelines in the Safety Data Sheet (SDS) available from Decon7 Systems LLC for information on the safe use, handling and disposal of this product.

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D7 Foaming Hand Sanitizer

Benzalkonium chloride based Hand Sanitizers have distinct advantages over gelled alcohol hand sanitizers. While both product forms are 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 benzalkonium chloride based hand sanitizers demonstrated greater sustained degerming activity than gelled alcohol gel 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). Leave-on Hand Sanitizers should not be used as a substitute for proper hand washing and hygiene practices.

D7 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.

Marketing Instructions from D7 Foaming Hand Sanitizer

D7 Foaming Hand Sanitizer NSF E3 for Food Handlers Registration does not include a fragrance. Do not include a fragrance when as NSF E3 Registered for Food Handlers. Additional NSF requirements, including labeling, apply. Contact Decon7 Systems LLC for more detailed information.

Drug Facts

Active ingredient	***Purpose***
Benzalkonium Chloride 0.1%	Antimicrobial

Uses ▪ For hand sanitizing to decrease bacteria on the skin ▪ Recommended for repeated use

Warnings

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 help or contact a Poison Control Center right away.

Directions ▪ 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, cetrimonium chloride, laurtrimonium chloride, dihydroxyethyl cocamine oxide, glycereth-17 cocoate, citric acid, fragrance

When marketing D7 Foaming Hand Sanitizer as an OTC Antiseptic, FDA Drug Facts Labeling and OTC Drug Manufacturing guidelines must be followed. The Drug Facts label illustrated here for D7 Foaming Hand Sanitizer, is an example of appropriate labeling for this use pattern.

Refer to FDA "Guidance for Industry Labeling OTC Human Drug Products" at http://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/uc m078792.pdf for detailed information on Drug Facts labeling.

Refer to (59 FR 31402) 21 CFR Parts 333 and 369 Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule, FDA- [Docket No. 75N-183H], RIN 0905-AA06 for specific use pattern guidelines.

In general, any claim that suggests that a product affects the structure or function of the body is a drug claim. Depending on the claim it may fall within an OTC monograph or may require an NDA. NDA claims, which are outside the scope of D7 include: disease prevention, antiviral, antifungal, residual antimicrobial protection, or helps heal skin or helps heal irritation.

Contact Decon7 Systems LLC for Canadian registration, and more details on labeling, manufacturing and regulatory information. See additional labeling requirements on the **D7 Foaming Hand Sanitizer Fact Sheet.**

D7 Foaming Hand Sanitizer Fact Sheet

D7 Foaming Hand Sanitizer's original formulation, 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 bacteria 99.9999% in as little as 15 seconds.

D7 Foaming Hand Sanitizer is recognized as being in compliance with the FDA Tentative Final Monograph for OTC Hand Sanitizer preparations (leave-on sanitizers not requiring a rinse) through prior use.

We've received numerous questions regarding D7 Foaming Hand Sanitizer, and the marketing environment for these types of products. Summarized below are some general answers:

What are the FDA Regulatory issues relating to Leave-On Antiseptic Products?

One question that folks will have relates to the choice of quat active ingredient, either benzalkonium chloride or benzethonium chloride, and recent issues relating to them. With regard to benzalkonium chloride or benzethonium chloride and the Agency, note that both quats are listed in the Antiseptic monograph as Category III for safety and efficacy. Category III for safety and efficacy means FDA did not have sufficient efficacy and safety information to list them as Category I for hand antisepsis. However, this category allows them to be marketed in products that fall within the monograph as long as the formulations conform to the percentage ranges in the monograph (Benzethonium = 0.1-0.2%; Benzalkonium = 0.1-0.13%). D7 Foaming Hand Sanitizer is in compliance with 0.1-0.13% benzalkonium chloride.

Status of Benzalkonium Chloride

A wash off Benzalkonium Chloride offering in the ranges of 0.1-0.13% is recognized under the 1994 TFM for Antiseptic Drug Products when making claims against bacteria. Its leave-on or hand sanitizer use without a rinse is recognized and covered by the OTC Drug Review for antiseptic handwash, healthcare-personnel handwash, and surgical scrub uses, with the through requisite prior evidence of it being marketed for a material time and extent prior to December 1975 in the United States for these uses. Therefore, until a final antiseptic monograph is issued and establishes Benzalkonium Chloride in Category I or Category II its (0.1-0.13%) remains in Category III and is allowed to be marketed as a wash-off (rinse) offering per the TFM or as a leave on because of being in the market prior to December 1975, i.e. Bactine®, developed in 1947 and introduced in 1950.

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.

Benzalkonium chloride has a long history of bactericidal, virucidal and fungicidal use in OTC Skin and Wound Treatment products such as Bactine®, EPA Registered Hard Surface disinfectants such as Lysol® brand disinfectants, and as a disinfectant active ingredient is effective against a wide range of pathogenic bacteria and viruses. Benzalkonium chloride (alkyl dimethyl benzyl ammonium chloride) is the most common algaecidal active ingredient in swimming pool algaecides, and has FDA Clearances as no-rinse Food Contact sanitizers for applications as varied as Bar Glass sanitizers, Ice Machine and Food Processing equipment sanitizers. Benzalkonium chloride has also been used as a preservative in eye drop products, and closely related materials as an anti-septic mouth wash. The Cosmetic Ingredient Review (CIR) Expert panel concludes that benzalkonium chloride is safe as a cosmetic ingredient at 0.1%.

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.

What are the advantages of Benzalkonium chloride-based over Alcohol-based Hand Sanitizers?

Benzalkonium chloride based Hand Sanitizers have several distinct advantages over alcohol-based hand sanitizers. While both product forms are fast acting and allow for use without water or towels, benzalkonium chloride based products are non-flammable, non-damaging to skin, are persistent, and will not stain clothing or flooring.

Safety- D7 Foaming Hand Sanitizer benzalkonium chloride-based instant 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 Purell 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.

Effectiveness and residual activity- Alcohol-based hand sanitizers stop working the instant they dry. The leading manufacturer of alcohol-based hand sanitizers claims that their product kills 99.99% of most common germs that may cause disease in as little as 15 seconds. Alcohol-based hand sanitizers dry in 8-10 seconds and fall below the efficacious concentration of alcohol in seconds. It has been reported that alcohol-based hand sanitizers offer no residual protection, and that if your hands feel dry after rubbing them together for 15 seconds, an insufficient volume of alcohol gel was likely applied (1). D7 Foaming Hand Sanitizer benzalkonium chloride-based hand sanitizer dries fast, but 10-15 seconds slower than alcohol-based hand sanitizers allowing more than the minimum contact time for complete efficacious coverage, including under fingernails.

Published studies report that benzalkonium chloride-based hand sanitizers demonstrated greater sustained antibacterial activity than gelled alcohol-based 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-based products.

In the referenced study to simulate repeated usage, alcohol-based and alcohol-free benzalkonium chloride-based hand sanitizers were compared. In the study, subject's hands were repeatedly inoculated with bacteria followed by application of hand sanitizer, then evaluated for antimicrobial effectiveness. The antimicrobial efficacy of the alcohol-based hand sanitizer showed a markedly decreased antimicrobial efficacy with subsequent contamination and decontamination cycles, whereas the alcohol-free benzalkonium chloride-based hand sanitizer showed a steady increase in antibacterial efficacy.

In addition to these objective results, subjects were asked to subjectively evaluate the condition of their hands after the completion of the test protocol. 47% of the subjects who had completed the test protocol with the alcohol-based hand sanitizer reported palmar pain or discomfort, and tended to indicate some discomfort in palmar surfaces for one to several days after the test. In contrast, none of the subjects that used the alcohol-free benzalkonium chloride-based formula reported any pain or discomfort of their hands after completing the test protocol(2).

In summary:

- Benzalkonium chloride-based hand sanitizers had a greater sustained antibacterial activity than alcohol-based hand sanitizers.
- Alcohol-based hand sanitizers became less effective with repeated use and irritated the hands of subjects.
- Benzalkonium chloride-based hand sanitizers became more effective without irritation after repeated use.

(1) Marples, RR, & Towers, AG (1979). A laboratory model for the investigation of contact transfer of microorganisms. *The Journal of Hygiene*, 82(2), 237-248.
(2) Dyer, DL, Gerenraich, KB, & Wadhams, PS (1998). Testing a new, alcohol-free sanitizer to combat infection. *Association of Operating Room Nurses Journal*, 68(2), 239-251.

NSF Approval

D7 Foaming Hand Sanitizer is NSF Registered under Category E3 for Food Handlers:

"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."

Is D7 Foaming Hand Sanitizer Effective?

D7 Foaming Hand Sanitizer is very effective, significantly exceeding the minimum requirements of 99.9% reduction in 60 minutes. D7 Foaming Hand Sanitizer Time-Kill data illustrate this effectiveness after just 15 seconds contact. Longer contact times result in greater % reduction, which is a significant property when comparing with alcohol-based hand sanitizers that lose activity instantly through evaporation, typically losing all activity in less than 15 seconds. The minimal loss of activity can mean the difference between a 99.999% reduction and 99.9%. This difference is VERY SGINIFICANT. If you start with a million pathogenic bacteria, a product that kills 99.999% could leave 100 viable organisms. Similarly, a product that kills 99.9% leaves 100,000 viable organisms – 1000 fold more. Fortunately, there are rarely a million pathogenic bacteria on hands. However, there can easily be 10,000 – 100,000, so the difference is in percent reductions becomes the difference between no survivors at 99.999% reduction and 1,000 – 10,000 at 99.9% reduction – which is the difference between non-infectious hands and highly infectious hands.

D7 Foaming Hand Sanitizer is very efficient at reducing bacteria on the skin, effective against a broad range of pathogenic bacteria in as little as 15 seconds as the Chlorine Equivalency and Time Kill Data below illustrate:

Chlorine Equivalency Test - Official Methods of Analysis of the AOAC, Sixteenth Edition, 1995. Chapter 6 – Disinfectants, 955.16 Chlorine (Available) in Disinfectants, Germicidal Equivalent Concentration. The object of this test is to determine the available chlorine germicidal equivalent concentration of the product as compared to 200, 100 and 50 ppm available chlorine in the NaOCl standard controls.

Initial Suspension Population
Staphylococcus aureus ATCC 6538 1.9 X 108 CFU/ml*
Salmonella typhi ATCC 6539 1.2 X 108 CFU/ml

*Colony Forming Units per ml of test mixture

Test Organism	Test Substance	Concentration	Subculture Series									
			1	2	3	4	5	6	7	8	9	10
S. aureus	NaOCl Control	200 ppm	0	0	0	0	0	0	0	0	+	+
		100 ppm	0	0	0	0	0	+	+	+	+	+
		50 ppm	0	+	+	+	+	+	+	+	+	+
	D7 Foaming Hand Sanitizer	RTU	0	0	0	0	0	0	0	0	0	0
S. typhi	NaOCl Control	200 ppm	0	0	0	0	0	0	0	+	+	+
		100 ppm	0	0	0	0	0	+	+	+	+	+
		50 ppm	0	+	+	+	+	+	+	+	+	+
	D7 Foaming Hand Sanitizer	RTU	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 test organism.

Chlorine Equivalency Test Efficacy Result

D7 Foaming Hand Sanitizer demonstrated an available chlorine equivalent to greater than the 200 ppm NaOCl standard control when tested against Staphylococcus aureus and Salmonella typhi.

Is D7 Foaming Hand Sanitizer Safe for Use?

D7 Foaming Hand 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 D7 Foaming Hand Sanitizer	
Acute Oral LD_{50}	>5.0 g/kg, Category IV
Acute Dermal LD_{50}	>2.0 g/kg, Category III
Eye Irritation	Category III
Skin Irritation	Category IV
Sensitization	Not a Skin Sensitizer

What about Benzethonium chloride based products?

As a side note regarding Benzethonium chloride, Grandfathering status has not yet been established for benzethonium chloride, because of no recorded use for a material time and extent prior to December, 1975. For now anyway, manufacturers/marketers of benzethonium chloride based leave-on hand sanitizer products (products not requiring a rinse) face FDA Enforcement action.

Why D7 Foaming Hand Sanitizer?

D7 Foaming Hand 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.

Time Kill Assay - American Society for Testing and Materials (ASTM). E2315-03, Guide for Assessment of Microbiocidal Activity Using a Time-Kill Procedure, Volume 11.05, Copyright 2005 ASTM International. A 0.1 ml aliquot of Staphylococcus aureus (Gram-positive coccus) and Pseudomonas aeruginosa (Gram- negative) bacterial cell suspensions were individually exposed to 9.9 mL of test substance (D7 Foaming Hand Sanitizer). Following a 15 second, 30 second and 1 minute exposure, a 1 mL aliquot of the inoculated sample of D7 Foaming Hand Sanitizer was transferred to a neutralizer to inactivate further antimicrobial activity. The neutralized sample was then assayed for survivors using a standard microbiological plate count procedure. Parallel to the test, a population control was performed using an inert diluent in place of the test substance to determine that actual number of organisms inoculated into the D7 Foaming Hand Sanitizer sample during the test. Following incubation, the surviving organisms were enumerated. Percent and log reduction values were then calculated as compared to the population controls. Appropriate purity, sterility, and neutralization controls were also performed. Data Summarized in the following table:

Time Kill Assay Results

This study demonstrates that D7 Foaming Hand Sanitizer is an effective Topical Antimicrobial effective against both Gram-Positive and Gram-negative bacterial pathogens. Data listed below is from an Exposure time of 15 Seconds:

Organism	Test Population Control (CFU/ml)	Number of Survivors (CFU/ml)	% Reduction	Log Reduction
Acinetobacter baumannii ATCC 19606	2.25×10^6	<5	>99.999	>5.65 Log_{10}
Enterococcus faecalis Vancomycin Resistant (VRE) ATCC 51575	1.45×10^6	<5	99.999	>5.46 Log_{10}
Escherichia coli ATCC 11229	3.4×10^6	2×10^1	99.999	5.23 Log_{10}
Escherichia coli O157:H7 ATCC 35150	3.3×10^6	2×10^1	99.999	5.22 Log_{10}
Klebsiella pneumoniae ATCC 4352	2.19×10^6	7.9×10^3	99.6	2.44 Log_{10}
Klebsiella pneumoniae NDM -1 positive CDC 1000527 ("New Dehli" superstrain)	2.21×10^6	<5	>99.9999	>5.64 Log_{10}
Listeria monocytogenes ATCC 19117	1.90×10^6	<5	>99.999	>5.58 Log_{10}
Pseudomonas aeruginosa ATCC 15442	1.64×10^6	<5	>99.999	>5.51 Log_{10}
Salmonella enteritidis ATCC 4931	2.48×10^6	<5	>99.999	>5.69 Log_{10}
Salmonella enterica serotype paratyphi B ATCC 8759	2.42×10^6	1×10^1	>99.999	5.38 Log_{10}
Salmonella enterica serotype pullorum ATCC 19945	1.31×10^6	1×10^1	99.999	5.12 Log_{10}
Salmonella enterica serotype typhimurium ATCC 23564	5.3×10^6	<5	>99.9999	>6.02 Log_{10}
Salmonella typhi ATCC 6539	1.72×10^6	<5	>99.999	>5.54 Log_{10}
Shigella dysenteriae ATCC 13313	1.52×10^6	<5	>99.999	>5.48 Log_{10}
Shigella flexneri ATCC 12022	1.41×10^6	5×10^1	>99.99	4.45 Log_{10}
Shigella sonnei ATCC 25931	5.9×10^5	<5	>99.999	>5.07 Log_{10}
Staphylococcus aureus ATCC 6538	1.82×10^6	2.7×10^2	>99.9	3.83 Log_{10}
Staphylococcus aureus Community Associated Methicillin Resistant (MRSA) NARSA NRS 123, Genotype USA400	1.25×10^6	<5	>99.999	>5.40 Log_{10}
Staphylococcus epidermidis ATCC 12228	9.0×10^5	<5	>99.999	>5.25 Log_{10}
Streptococcus equi ssp. Equi ATCC 33398	1.27×10^7	<5	>99.9999	>6.40
Vibrio cholera ATCC 11623	1.49×10^5	<5	>99.99	>4.47 Log_{10}
Yersinia enterocolitica ATCC 23715	5.5×10^6	1×10^1	>99.999	5.74 Log_{10}