Vetbac™

Instant Foam Hand Sanitizer

Vetbac Instant Foam Hand Sanitizer is based on the active ingredient Benzalkonium Chloride in a unique foaming, non-drying, moisturizing and conditioning, Patent-Pending formulation. The efficacy of this product has been confirmed to reduce S. aureus 99.99% in as little as 15 seconds. Benzalkonium Chloride, is listed in the Antiseptic monograph as Category III for safety and efficacy.

Properties

Physical form	Light amber liquid
Benzalkonium chloride, active %	0.10
Assay (Epton), meq/kg	6.1-6.9
pH	5.0-7.0
Specific Gravity @25°C	1.00±0.02
Flash point (PMCC)	>200°F(>93°C)

Benzalkonium chloride based Hand Sanitizers have distinct advantages over gelled alcohol hand sanitizers. While both product forms are FDA Monograph compliant for leave on products, 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 gelled alcohol hand sanitizers actually make 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. Benzalkonium chloride, unlike benzethonium chloride, is the only quat active 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.

Patent Pending Vetbac™ 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.

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, dihydroxypropyl PEG-5 linoleammonium chloride, glycereth-2 cocoate, behentrimonium chloride, dihydroxyethyl cocamine oxide, fragrance

Vetbac Fact Sheet

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

One question you may 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. Benzalkonium chloride has been Grandfathered in its acceptability as a hand sanitizer. Grandfathering status, however, has not yet been established for benzethonium chloride. This is because of no recorded use for the material time and extent prior to December, 1975. For the present, manufacturers/marketers of benzethonium chloride based leave-on hand sanitizer products (products not requiring a rinse) face FDA Enforcement action.

Why Vetbac?

Patent-Pending Vetbac™ Instant 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.

Is Vetbac Safe for Use?

Vetbac™ Instant 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 Vetbac Instant Hand Foam 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

Is Vetbac Effective?

Vetbac™ Instant 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 Equivalancy Test

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 — 7.6×10^8 CFU/ml* *Colony Forming Units per ml of test mixture
Salmonella typhi ATCC 6539 — 1.2×10^8 CFU/ml

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	+	+	+	+	+
		100 ppm	0	0	+	+	+	+	+	+	+	+
		50 ppm	0	+	+	+	+	+	+	+	+	+
	Vetbac	RTU	0	0	0	0	0	0	0	0	0	0
S. typhi	NaOCl Control	200 ppm	0	0	0	0	0	0	+	+	+	+
		100 ppm	0	0	0	+	+	+	+	+	+	+
		50 ppm	0	0	+	+	+	+	+	+	+	+
	Vetbac	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.

Efficacy Result

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

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

Organism	Test Population Control (CFU/ml)	Number of Survivors (CFU/ml)	% Reduction	Log Reduction
Campylobacter jejuni ATCC 29428	1.02×10^{7}	$<1 \times 10^{2}$	>99.999	>5.00 Log_{10}
Candida albicans ATCC 10231	1.60×10^{5}	6.0×10^{3}	96.3	1.42 Log_{10}
Clostridium difficile ATCC 9689	3.40×10^{6}	<2	>99.9999	>6.20 Log_{10}
Enterococcus faecalis Vancomycin Resistant (VRE) ATCC 51575	1.12×10^{6}	3.2×10^{1}	99.99	4.54 Log_{10}
Escherichia coli ATCC 11229	3.80×10^{6}	4	99.999	6.00 Log_{10}
Escherichia coli O157:H7 ATCC 35150	1.26×10^{6}	<2	>99.999	>5.80 Log_{10}
Klebsiella pneumoniae ATCC 4352	1.10×10^{6}	2	99.999	5.70 Log_{10}
Listeria monocytogenes ATCC 19117	4.7×10^{6}	1.9×10^{3}	99.9	3.39 Log_{10}
Pseudomonas aeruginosa ATCC 15442	3.5×10^{6}	<2	99.9999	>6.20 Log_{10}
Salmonella choleraesuis serotype enteritidis ATCC 4931	6.8×10^{5}	2	>99.999	5.50 Log_{10}
Salmonella choleraesuis serotype paratyphi ATCC 8759	5.6×10^{5}	<2	>99.999	>5.50 Log_{10}
Salmonella choleraesuis serotype pullorum ATCC 19945	8.9×10^{5}	<2	>99.999	>5.70 Log_{10}
Salmonella choleraesuis serotype typhimurium ATCC 23564	7.7×10^{5}	6	>99.999	>5.10 Log_{10}
Salmonella typhi ATCC 6539	1.27×10^{6}	2	99.999	5.80 Log_{10}
Shigella dysenteriae ATCC 13313	1.3×10^{6}	<2	>99.999	>5.80 Log_{10}
Shigella flexneri ATCC 12022	1.39×10^{6}	2.8×10^{1}	99.99	4.69 Log_{10}
Shigella sonnei ATCC 25931	2.43×10^{7}	2.0×10^{1}	99.9999	6.09 Log_{10}
Staphylococcus aureus ATCC 6538	6.7×10^{6}	<2	>99.9999	>6.53 Log_{10}
Staphylococcus aureus Methicillin Resistant (MRSA) ATCC 33592	1.23×10^{7}	3.8×10^{3}	>99.9	3.51 Log_{10}
Staphylococcus epidermidis ATCC 12228	7.2×10^{5}	<2	99.999	5.56 Log_{10}
Streptococcus pneumonia ATCC 6305	6.4×10^{5}	<2	>99.999	>5.51 Log_{10}
Streptococcus pyogenes ATCC 19615	1.77×10^{6}	<2	>99.999	>5.90 Log_{10}
Vibrio cholera ATCC 11623	4.7×10^{5}	<2	>99.999	>5.40 Log_{10}
Xanthomonas axonopodis (Citrus Canker) ATCC 49118	1.28×10^{6}	3.6×10^{1}	>99.99	4.55 Log_{10}
Yersinia enterocolitica ATCC 23715	2.23×10^{6}	3.8×10^{1}	99.99	4.77 Log_{10}