



Mason Chemical Company



Nobac[®]

Instant Foam Hand Sanitizer 10X Concentrate

- Effective against MRSA
- NSF E3 approved for Food Handlers

Overview

Nobac[®] Instant Foam Hand Sanitizer is based on the active ingredient Benzalkonium Chloride in a unique non-drying, moisturizing and conditioning, Patented formulation. NSF Approved E3 for no-rinse hand sanitizing, Nobac kills 99.9% of most common germs that may cause illness, including E. Coli and MRSA in just 15 seconds. Nobac Instant Foaming Hand Sanitizer is available in a 10X Concentrate, prepared and shipped from our FDA Registered Establishment, for dilution, addition of fragrance, and packaging in under your name.

Benzalkonium Chloride, which 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 conform to the percentage ranges in the monograph, which is 0.1-0.13% for Benzalkonium chloride. As in the case of Ethanol based Instant Hand Sanitizers, Benzalkonium chloride based products qualify for monograph "grandfathering" with a demonstrated use pattern established for a material time and extent prior to December, 1975.

Typical Properties

	<u>Nobac 10X Conc.</u>	<u>Nobac RTU</u>
Physical form.....	Amber liquid	Light amber liquid
Benzalkonium chloride, active %	1.0	0.1
Assay (Epton), meq/kg.....	62.0-72.0	6.2-7.2
pH.....	5.0-7.0	5.0-7.0
Specific Gravity @25°C	1.00±0.02	1.00±0.02
Flash point (PMCC).....	>200°F(>93°C)	>200°F(>93°C)

Handling Information

Note - Manufacturing, Packaging and Marketing of this product may be subject to regulation by the Food and Drug Administration and may be subject to Enforcement Action. Contact Mason Chemical Company for details.

Refer to and follow the guidelines in the Material Safety Data Sheet (MSDS) available from Mason Chemical Company for information on the safe use, handling and disposal of this product.

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Nobac®

Instant Foam Hand Sanitizer 10X Concentrate

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, 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). 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.

Patented Nobac® 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 afterfeel, and does not contain polymer thickeners or silicones.

Formula and Mixing Instructions from Nobac® 10X Concentrate

Ingredient	Weight %	
Nobac 10X Concentrate	10.0	
Fragrance ¹	0.1	Add Fragrance to Nobac 10X Concentrate with mild agitation. Continue to agitate until uniform.
Water	89.9	Add Water to Nobac 10X Concentrate/Fragrance solution with mild agitation. QA, then package.

- (1) Nobac Fragrance #103099
Intarome Fragrance & Flavor Corporation, 370 Chestnut Street, Norwood, NJ 07648. Ph: 800-631-1566

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

When marketing Nobac Instant Foam 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 Nobac, is an example of appropriate labeling for this use pattern.

Refer to FDA "Draft Guidance for Industry Labeling OTC Human Drug Products" at <http://www.fda.gov/cder/guidance/5008dft.htm> 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 Nobac include: antiviral, antifungal, residual antimicrobial protection, or helps heal skin or helps heal irritation.

Contact Mason Chemical Company for Canadian registration, and more details on labeling, manufacturing and regulatory information.

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Nobac Fact Sheet

Nobac® Instant Foam Hand Sanitizer, based on the active ingredient Benzalkonium chloride, is a unique Patented 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.

Nobac Instant Foam Hand Sanitizer is in compliance with the FDA Final Tentative Monograph for OTC Hand Sanitizer preparations (leave-on sanitizers not requiring a rinse), and registered in Canada. Nobac Instant Foaming Hand Sanitizer is available in a 10X Concentrate, prepared and shipped from our FDA Registered Establishment, for dilution, addition of fragrance, and packaging in your FDA Registered Establishment, or the FDA Registered Establishment of your choice, under your name. We are currently filling orders for Nobac 10X Concentrate.

We've received numerous questions regarding Nobac, 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 antiseptics. 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% - note this is hard to track in the monograph but we have confirmed it with FDA). Nobac Instant Hand Sanitizer is in compliance with 0.1% benzalkonium chloride.

Even though the monograph is tentative, products must follow FDA labeling and manufacturing requirements, but due to case law, the types and extent of efficacy testing is not being enforced. While Mason Chemical has generated formulation specific efficacy data confirming Nobac, and is generating additional formulation specific efficacy data to support Nobac within industry practice guidelines, we may be required to generate additional efficacy data when the Monograph becomes final.

Now, the real issue is that FDA does not feel that the 1994 TFM includes hand sanitizers (e.g. waterless or leave-on products). Though there are many paragraphs within the monograph that suggest otherwise, this is the stance of the Office of Enforcement. So, today, you can market a quat wash-off product within the above ranges and complying with the above regulations without concern. However, since the hand sanitizer use pattern is not part of the monograph in the eyes of Office of Enforcement, the product may only be on the monograph with an NDA or if it qualifies for what is called "grandfathering". A product may be grandfathered, if records can be shown that it was in the market for a material time and extent prior to December, 1975. Enforcement did the research to prove that this was true for ethanol hand sanitizers thus they are "grandfathered". Recently, FDA enforcement staff shared with us that they have been shown information to allow grandfathering of IPA, IPA and Ethanol combinations, and benzalkonium chloride. Benzalkonium chloride "grandfathering" has been confirmed, and FDA enforcement staff verbally stated to us that thus they plan no further regulatory action against waterless benzalkonium products that comply with the other items listed above.

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.

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 FDA Monograph for leave-on products, 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- Nobac 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.



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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⁾. Nobac 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. Additionally, benzalkonium chloride-based hand sanitizers deliver 2 to 4 hours of residual protection.

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, an alcohol-based and alcohol-free benzalkonium chloride-based hand sanitizer 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.

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 Nobac?

Patented Nobac® 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.

NSF Approval

Nobac is NSF Registered (NSF Registration No. 138902) 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.”

Contact Mason Chemical Company regulatory support for details regarding NSF E3 specific labeling and registration.

What about Nobac in Canada?

Nobac® Instant Foaming Hand Sanitizer is registered in Canada with DIN# 02291304 as Mason Hand Sanitizer. As with Mason's registered disinfectant formulations, companies with Mason sub-registrations that want to sell in Canada need to apply for their own Canadian registrations. Mason simplifies this process by registering our disinfectant formulations first. We do this with our key disinfectant registrations, and we've done this with Nobac. By having Nobac (Mason Hand Sanitizer in Canada) registered in Canada, and granting an Authorization for the Canadian Regulatory Authority's use and reference of our data in support of the customer's individual registration, the customers save time and money.

We are recommending the Registration/Consulting firm Dell Tech Laboratories, Ltd. for handling the individual customer registration applications. The Dell Tech folks are quite experienced in this process, and have handled the registration process for Nobac in Canada, as well as our registered disinfectants.

All our customers need to do is contact Dell Tech Laboratories, and let them know they want a Mason Hand Sanitizer (Nobac) copy registration. They'll need to contract with Dell Tech directly for related expenses. The contact information for Dell Tech is:

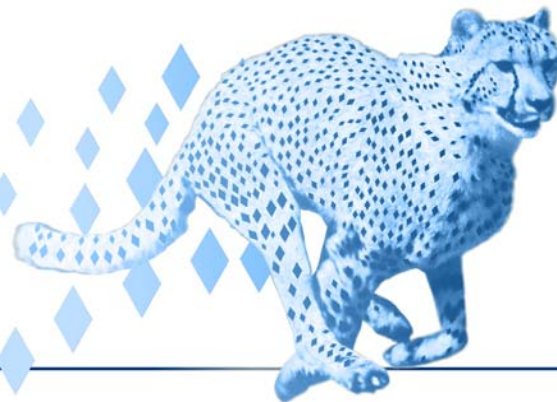
Dell Tech Laboratories, Ltd.
UWO Research Park
100 Collip Circle
London, Ontario N6G 4X8
Canada

Terry Dickinson
519-858-5068
tdickinson@delltech.com

Contact Mason Chemical Company regulatory support for details regarding bi-lingual labeling and registration in Canada.



Mason Chemical Company



Where can I source the foam dispensers?

Airspray International Incorporated
3768 Park Central Blvd.
North Pompano Beach, FL 33064
Phone: 954-972-7750
Fax: 954-972-7797
Web: www.airspray.net

Where can I obtain FDA/GMP consulting expertise for setting-up my plant for Nobac?

SRC
PO Box 1014
Columbia City, IN 46725
Phone: 260-244-6270
Email: shays@srcconsultants.com
Web: www.srcconsultants.com

Where can I have Nobac packaged?

Contact Mason Chemical for the expanding list of FDA Registered OTC packagers.

Where can I source labels?

RLG Resource Label Group
147 Seaboard Lane
Franklin, TN 37067
Phone: 615-661-5900
Email: tperry@resourcelabel.com
Web: www.resourcelabel.com

Rely on Mason Chemical Company as the Quaternary Experts for processing and manufacturing support, extensive regulatory experience in label development, and reliable customer service.

Is Nobac Effective?

Nobac® 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:

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

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Chlorine Equivalency 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 X 10⁸ CFU/ml* *Colony Forming Units per ml of test mixture

Salmonella typhi ATCC 6539 1.2 X 10⁸ CFU/ml

Test Organism	Test Substance	Concentration	Subculture Series									
			1	2	3	4	5	6	7	8	9	10
<i>S. aureus</i>	NaOCl Control	200 ppm	0	0	0	0	0	0	+	+	+	+
		100 ppm	0	0	+	+	+	+	+	+	+	+
		50 ppm	0	+	+	+	+	+	+	+	+	+
	Nobac	RTU	0	0	0	0	0	0	0	0	0	0
<i>S. typhi</i>	NaOCl Control	200 ppm	0	0	0	0	0	0	+	+	+	+
		100 ppm	0	0	0	+	+	+	+	+	+	+
		50 ppm	0	0	+	+	+	+	+	+	+	+
	Nobac	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

Nobac 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*.

Is Nobac Safe for Use?

Nobac® 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 Nobac Instant Hand Foam Sanitizer		Toxicity Profile Nobac 10X Concentrate	
Acute Oral LD ₅₀	>5.0 g/kg, Category IV	Acute Oral LD ₅₀	>5.0 g/kg, Category IV
Acute Dermal LD ₅₀	>2.0 g/kg, Category III	Acute Dermal LD ₅₀	>2.0 g/kg, Category III
Eye Irritation	Category III	Eye Irritation	Category I
Skin Irritation	Category IV	Skin Irritation	Category IV
Sensitization	Not a Skin Sensitizer	Sensitization	Not a Skin Sensitizer

Visit our website at www.masonsufactants.com for more information on this product and others.

Test Method for Nobac (titration)

Nobac actives (Benzalkonium Chloride) concentration can be inferred by titration. Nobac 10X Certificate of Analysis reports Benzalkonium Chloride Active concentration (determined directly by HPLC⁽¹⁾), and a titration result for total cationic species (Nobac contains 3 cationic materials including the active benzalkonium chloride) expressed in meq/kg. Dilution of the total cationic species 10X will necessarily dilute the active benzalkonium chloride 10X. For example: the specification for total cationics by the Epton procedure is 62.0-72.0 meq/kg. A typical Certificate of Analysis might report a value of 65.0 meq/kg with an active Benzalkonium Chloride concentration of 1.1%. Dilution 10X of this Nobac 10X Concentrate to 6.5 meq/kg will result in $6.5/65.0 \times 1.1\%$ Benzalkonium Chloride = 0.11% Benzalkonium Chloride.

Epton Procedure

Reagents needed for the test:

- Hyamine 1622 solution, 0.004M
- Sodium Lauryl Sulfate 0.003N, standardized against Hyamine 1622 solution
- Chloroform, A.R. Grade
- Salt Buffer Solution – Prepare by adding 7 grams of sodium carbonate, 100 grams of sodium sulfate to 1000ml distilled water.
- Methylene blue indicator solution (1.0% w/v in Denatured Alcohol)

Apparatus needed for the test:

- 1000ml volumetric flask
- Analytical balance
- Graduated cylinder, 50-100ml capacity
- Burette, 25-50ml
- 250ml stoppered graduated cylinder

Procedure:

1. Catch weigh into a 250 ml stoppered graduated cylinder 10 grams of Nobac, or 1 gram of Nobac 10X (to the nearest 0.0001 grams) and record weight.
2. Add 50 ml of chloroform, 50 ml of salt buffer solution and 1 drop of methylene blue indicator to the 250 ml stoppered graduated cylinder.
3. Stopper the cylinder and shake the solution vigorously. Initial solution is blue in the upper phase and a slight pink to clear in the lower phase.
4. Titrate with the 0.003N sodium lauryl sulfate solution. Titrate to a colorless end-point in the upper phase of solution when viewed before direct light. Lower phase is dark blue. Titration in duplicate is recommended.

Note: Add several mls of titrant initially, (to within about 80% of the target) and then reduce increments progressively to a few drops until reaching the endpoint. Stopper the cylinder after each addition of titrant and shake vigorously. Release the pressure carefully by opening the stopper. Allow mixture to separate into two layers after each shaking. A rapid breaking of the emulsion and development of blue color in the lower phase indicates the approach of the end point.

Calculation:

$$\text{meq/kg} = [(\text{mls SLS solution} \times \text{N of SLS solution}) / \text{sample weight}] \times 1000$$

(1) Application of the HPLC method for benzalkonium chloride determination in aerosol preparations, J. Dudkiewicz-Wilczynska, J. Tautt, I. Roman, J. Pharm. Biomed. Anal. 34 (2004) 909-920.

[Available online at www.sciencedirect.com]