



Nobac™

Instant Foam Hand Sanitizer 10X Concentrate

Overview

Nobac™ Instant Foam Hand Sanitizer is based on the active ingredient Benzalkonium Chloride in a unique 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. 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.....	61.0-69.0	6.1-6.9
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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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 gelled alcohol gel 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 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. Warm if necessary.*
Water	89.9	Add Water to Nobac 10X Concentrate/Fragrance solution with mild agitation. Continue to agitate until uniform. QA, then package.

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

Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.1%	Antimicrobial
Uses <ul style="list-style-type: none"> ▪ 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 <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	

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 and requirements.

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.

*Nobac 10X concentrate will become hazy and may separate when stored cold. Gently warm prior to use, with agitation if necessary, to obtain uniform solution. Contact Mason Chemical Company for more details on labeling, manufacturing and regulatory information.

Nobac Fact Sheet

Nobac™ Instant Foam Hand Sanitizer, based on the active ingredient Benzalkonium chloride, is a unique Patent-Pending formulation featuring exceptional skin feel, conditioning and moisturizing properties. The efficacy of this product has been confirmed to reduce *S. aureus* 99.999% 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). 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 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% - 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.

One last point regarding FDA:

One last point is that FDA Enforcement staff always makes the point with us that manufacturers get in trouble for labeling and manufacturing violations first, then with more scrutiny regulatory issues are piled on. Given this, and all of the above, we want to make sure that our customers fully understand the labeling and manufacturing issues regarding Nobac. By working with our customers to assure that all the regulations are followed, everyone's risk will be lower. Contact Mason with any questions.

Why Benzalkonium chloride based Hand Sanitizers?

Benzalkonium chloride based Hand Sanitizers have distinct advantages over gelled alcohol 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, less drying to skin, and will not stain clothing. Published studies report that gelled alcohol gel 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 is a 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.

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?

Patent-Pending 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.

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?

Webco Chemical Corporation
420 West Main Street
Dudley, MA 01571
Phone: 508-943-9500
Fax: 508-987-0366
Contact: Mark Ruggeri
Email: markr@webco-chemical.com

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

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:

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	+	+	+	+	+
		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*.

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 pneumoniae</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

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