

Technical Bulletin

Microsan_{rx} Foaming Hand Sanitizer

Microsan_{rx} Foaming Hand Sanitizer is a low alcohol, non-flammable hand sanitizer with a pH of 3.5 containing 13,000 ppm benzalkonium chloride and nonoxynol-9 for a rapid kill of 99.99% to 99.999% in 15 seconds contact time.

Physical Characteristics

Color: Clear

Fragrance: Cucumber Melon

Viscosity: As Water

pH: 3-4

Toxicity Profile

Microsan_{rx} 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

Dermatology and Safety

Primary Dermal Irritation: Six New Zealand white rabbits each received a single dermal application of 0.5 ml of the test product on two sites—one abraded and one intact. The test sites were occluded for 24 hours and observed individually for erythema, edema and other effects 24 hours and 72 hours post application. Mean scores from the 24 and 72 hour readings were averaged to determine the primary irritation index.

Findings: A dermal score of 0.21 was found which falls within the Draize bracket of 0.1 to 0.9. This score indicates a extremely slight irritation potential to humans.

Primary Ocular Irritation: Six New Zealand white rabbits, free from visible ocular defects, each received a single inter-ocular application of 0.1 gm of the test product in one eye. The contralateral eye, remaining untreated, served as a control. The eyes of all of the animals remained unwashed for 24 hours. Observations of corneal opacity, iritis and conjunctivitis were recorded at 24 hours, 48 hours, and 72 hours after treatment and at 4 and 7 days should irritation persist.

Findings: Ocular irritation test scores on the unwashed eye exposure, which is the criteria for ranking products, was 0.3. This score is the result of slight conjunctivae in two of the six rabbits and is interpreted to be practically non-irritating. Water wash out within 30 seconds reduced the score to 0.

Repeated Insult Patch Test: Because some products contact the skin on a repeated basis, human patch testing is done to determine if they cause irritation or if some sensitivity might develop. Fifty adult subjects, ranging in age from 21 to 73 were qualified and selected.

The upper back between the scapula served as the treatment area. Approximately 0.15 ml of test product was applied to the 1.5" x 2" gauze portion of the adhesive dressing. This was applied to the test site to form a semi-occlusive patch. The procedure was followed three times per week for a total of ten applications. The participants were instructed to remove these patches after 24 hours. Evaluations were made just prior to re-application.

At the conclusion of a fourteen day rest period following the tenth application, a challenge patch was applied to the original and a virgin site. Each site was evaluated at 24 and 48 hours after this application.

Findings: On a group of fifty human subjects these tests that under test conditions, there was no indication of dermal irritation or sensitization on varying skin types and ethnic groups.

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 65387. 6×10^8 CFU/ml* *Colony Forming Units per ml of test

Salmonella typhi ATCC 6539 1.2×10^8 CFU/ml

Test Organism	Test Material	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	+	+	+	+	+	+	+	+	+
	Microsan FHS	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	+	+	+	+	+	+	+	+
	Microsan FHS	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 Equivalence Result:

Microsan_{rx} Foaming Hand Sanitizer demonstrated an available chlorine germicidal equivalent concentration of the product when compared to 200, 100 and 50 ppm available chlorine in the NaOCl standard controls.

European Norm, EN 12054, and EN 1500 Efficacy Equivalence:

Microsan_{rx} has passed the EN 12054 and EN1500 protocols. These standardized testing protocols tested the efficacy of Microsan_{rx} Foaming Hand Sanitizer against the standard, 60% 2-propanol. All alcohol based gel hand sanitizers tested did NOT pass these test protocols. The testing was done by Hospital Infection Research Laboratory, Birmingham,UK.

**Bacteria and Yeast Testing.
99.99% to 99.999% Reduction
in 15 Seconds.**

Organism	ATCC #
Acinetobacter calcoaceticus var. anitratus	Clinical Isolates
Acinetobacter calcoaceticus var. woffii	Clinical Isolates
Actinobacillus pleuropneumonia	Clinical Isolates
Actinomyces pyogenes	19411
Bacillus anthracis (non-spores)	Soil Isolate
Bordetella bronchiseptica	Clinical Isolates
Bordetella bronchiseptica	19359
Brevibacterium ammoniagenes (in DI water)	Clinical Isolates
Campylobacter jejuni	29428
Candida albicans	Clinical Isolates
Clostridium difficile (non-spores)	Clinical Isolate
Corynebacterium pseudotuberculosis	19410
Cryptococcus neoformans	Clinical Isolates
Enterobacter aerogenes (in DI water)	Clinical Isolates
Enterobacter cloacae	Clinical Isolates
Enterobacter gergoviae	Clinical Isolates
Enterobacter liquefaciens	Clinical Isolates

Organism	ATCC #
Enterococcus faecalis	Clinical Isolates
Escherichia coli	Clinical Isolates
Escherichia coli 0157 :H7	Clinical Isolates
Escherichia vulneris	Clinical Isolates
Flavobacterium meningosepticum	Clinical Isolates
Hafnia alvei	Clinical Isolates
Klebsiella oxytoca	Clinical Isolates
Klebsiella pneumoniae	Clinical Isolates
Listeria monocytogenes	984
Micrococcus luteus	Clinical Isolates
Morganella morganii	Clinical Isolates
Pasturella haemolyticus	Clinical Isolates
Proteus mirabilis	Clinical Isolates
Proteus vulgaris	Clinical Isolates
Pseudomonas aeruginosa	Clinical Isolates
Pseudomonas cepacia	Clinical Isolates
Pseudomonas dimunita	Clinical Isolates
Pseudomonas fluorescens	Clinical Isolates
Pseudomonas paucimobilis	Clinical Isolates

Organism	ATCC #
Pseudomonas picketti	Clinical Isolates
Pseudomonas pseudomallei	Clinical Isolates
Pseudomonas putida	Clinical Isolates
Pseudomonas stutzeri	Clinical Isolates
Rhodococcus equi	6939
Salmonella schottmuelleri (in DI water)	Clinical Isolates
Salmonella choleraesuis	Clinical Isolates
Salmonella typhi	6539
Salmonella typhosa	Clinical Isolates
Serratia marcescens	Clinical Isolates
Shigella paradysenteriae flexnerii	Clinical Isolates
Stahylococcus aureus	Clinical Isolates
Staphylococcus aureus (toxic shock)	Clinical Isolates
Staphylococcus auricularis	Clinical Isolates
Staphylococcus capitis	Clinical Isolates
Staphylococcus epidermidis	Clinical Isolates
Staphylococcus hominis	Clinical Isolates
Staphylococcus saprophyticus	Clinical Isolates
Staphylococcus simulans	Clinical Isolates

Organism	ATCC #
Streptococcus agalactiae hemolytica	Clinical Isolates
Streptococcus haemolyticus	Clinical Isolates
Streptococcus hominis	Clinical Isolates
Streptococcus equi var. zooepidermicus	43079
Streptococcus equi var. equi	Clinical Isolates
Streptococcus faecalis	Clinical Isolates
Streptococcus haemolyticus	Clinical Isolates
Streptococcus haemolyticus (beta)	Clinical Isolates
Streptococcus pneumoniae	Clinical Isolates
Streptococcus pyogenes	Clinical Isolates
Streptococcus salivarius	Clinical Isolates
Streptococcus simulans	Clinical Isolates
Treponema pallidum	81136
Yersinia enterocolitica	Clinical Isolates

Antibiotic Resistant Bacteria:
99.99% to 99.999% Reduction
in 15 Seconds. All Clinical Isolates.

Organism	Drug
Enterobacter agglomerans	Ampicillin Sulfanilimide
Enterococcus faecalis	Vancomycin
Escherichia coli (Wound)	Tetracycline Ampicillin Sulfa
Escherichia coli (Urinary)	Sulfa Penicillin
Klebsiella oxytoca	Sulfanilimide Tetracycline
Klebsiella pneumoniae	Cephalothin Ampicillin Sulfa Tetracycline
Morganella morganii	Penicillin Tetracycline
Pseudomonas aeruginosa	Sulfa Cefatoxime Nitrofurantoin Amikacin Ampicillin Cephalothin Bactrim
Staphylococcus aureus	Methicillin Penicillin G Ampicillin Cefazolin Cefatoxime Chloramphenicol Ciprofloxacin Clindimycin Erythromycin Oxacillin Rifampin Tetracycline
Staphylococcus epidermidis	Ampicillin Chloramphenicol Erythromycin Oxacillin Bactrim Ciprofloxacin

Virus Testing: At Least
99.99% to 99.999% Reduction
in 15 Seconds.

Test Conditions: Virucidal Activity was Confirmed by an FDA/EPA Accepted Protocol Against the Following Viruses

Virus	ATCC#
Adenovirus Type 2 (In DI Water)	Clinical Isolate
Avian Influenza/Turkey/Wisconsin	VR-798
Cytomegalovirus	VR-284
HBV (Hepatitis B Virus)	Duck HBV
HCV (Hepatitis C Virus)	BVDV
Herpes Simplex Type 1 Virus (In DI Water)	Clinical Isolate
Herpes Simplex Type 2 Virus (In DI Water)	VR-734
HIV-1 (AIDS)	Clinical Isolate
Influenza A/Brazil Virus	Clinical Isolate
Influenza A2-Asian Virus (In DI Water)	Clinical Isolate
Influenza B Virus (Allen Strain)	VR-102
Influenza C Virus (Taylor Strain)	Clinical Isolate
Measles Virus	VR-24
Newcastle Disease Virus	VR-109
Parainfluenza Type 1 Virus	VR-105
Porcine Poliovirus	VR-742
Pseudorabies Virus	VR-135
Rotavirus	Clinical Isolate