

Sani-Cloth®

GERMICIDAL DISPOSABLE WIPE

AF3

EPA Reg. No. 9480-9



PRODUCT DESCRIPTION

Sani-Cloth® AF3 Germicidal Disposable Wipe is a nonwoven, disposable cloth, pre-saturated with a quaternary disinfectant. Recommended for use in hospitals and critical care areas where control of the hazards of cross contamination between treated surfaces is of prime importance. Use on hard, nonporous surfaces and equipment. Disinfects in just three (3) minutes.

CHEMICAL COMPOSITION

Active Ingredients:

n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	0.14%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	0.14%
Other ingredients.....	99.72%
TOTAL.....	100.00%

Each cloth is saturated with 2,800 parts per million of active quaternary ammonium chlorides.

EFFICACY

BACTERIAL ORGANISM EFFICACY

MULTI-DRUG RESISTANT BACTERIA:

Acinetobacter baumannii, Multi-Drug Resistant [ATCC 19606]
 ESBL Producing *Escherichia coli* (*E. coli*) [ATCC BAA-196]
Escherichia coli – NDM-1 Positive [CDC 1001728]
 ESBL Resistant *Klebsiella pneumoniae* [ATCC 700603]
Klebsiella pneumoniae - Carbapenem Resistant [ATCC BAA-1705]
Klebsiella pneumoniae - NDM-1 Positive [CDC 1000527]
 Community Acquired Methicillin Resistant *Staphylococcus aureus*
 (CA-MRSA) [NARSA NRS384] [Genotype USA 300]
 Community Acquired Methicillin Resistant *Staphylococcus aureus*
 (CA-MRSA) [NARSA NRS123] [Genotype USA 400]
 Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33592]
Streptococcus pneumoniae – Penicillin Resistant [ATCC 700677]
 Vancomycin Resistant *Staphylococcus aureus* (VRSA) [NARSA VRS1]
 Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51575]

Test Method Used: Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
 Organic Soil Load: 5% Fetal Bovine Serum
 Exposure Time: 3 minutes at 68-69.8°F
 Incubation: 2-8 days at 95-98.6°F
 Results: No growth observed

BACTERIA:

Bordetella bronchiseptica [ATCC 10580]
Bordetella pertussis [ATCC 12743]
Burkholderia cepacia [ATCC 25416]
Campylobacter jejuni [ATCC 29428]
Enterobacter aerogenes [ATCC 13048]
Escherichia coli [ATCC 11229]
Escherichia coli O157:H7 [ATCC 35150]
Klebsiella pneumoniae [ATCC 4352]
Listeria monocytogenes [ATCC 19111]
Proteus vulgaris [ATCC 9920]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC 10708]
Serratia marcescens [ATCC 14756]
Shigella dysenteriae [ATCC 11835]
Staphylococcus aureus [ATCC 6538]
Streptococcus pyogenes [ATCC 19615]
Vibrio cholera [ATCC 11623]
Yersinia enterocolitica [ATCC23715]

Test Method Used: Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
 Organic Soil Load: 5% Fetal Bovine Serum
 Exposure Time: 3 minutes at 68-69.8°F
 Incubation: 2-6 days at 95-98.6°F
 Results: No growth observed

MYCOBACTERIUM BOVIS - BCG (TB):

Test Method Used: Modified AOAC Tuberculocidal Method for Pre-saturated Towelettes for Hard Surface Disinfection
 Organic Soil Load: 5% Horse Serum
 Exposure Time: 3 minutes at 68°F
 Incubation: 90 days at 98.6°F
 Results: No growth observed

PATHOGENIC FUNGI EFFICACY

YEAST ORGANISM:

Candida albicans [ATCC 10231]

Test Method Used: Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
 Organic soil load: 5% Fetal Bovine Serum.
 Exposure Time: 3 minutes at 69.8°F
 Incubation: 3 days at 77.86°F
 Results: No growth observed

EFFICACY

VIRAL ORGANISM EFFICACY

ENVELOPED VIRUSES:

Avian Influenza A H5N1 virus [Strain VNH5N1-PR8/CDC-RG CDC #2006719965]
 Cytomegalovirus [ATCC VR-538], Strain AD-169
 Herpes simplex virus type 2 [ATCC VR-734], Strain G
 Human Coronavirus [ATCC VR-740], Strain 229E
 Influenza A virus/Hong Kong Strain [ATCC VR-544]
 *Pandemic 2009 H1N1 Influenza A virus (kill claim included)
 Influenza B virus, Strain B/Hong Kong /5/72 [ATCC VR-823]
 Respiratory syncytial virus (RSV) [ATCC VR-26], Strain Long

NON-ENVELOPED VIRUSES:

Adenovirus type 5 [Strain Adenoid 75] [ATCC VR-5]
 Rotavirus [Strain WA]

Test Method Used:

Tests were conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of test for determining the virucidal efficacy of disinfectants intended for use on dry inanimate surfaces.

Organic soil load:

5% Fetal Bovine Serum.

Exposure Time:

3 minutes at 68°F

Results:

Virucidal according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

BLOODBORNE PATHOGENS:

Hepatitis B virus (HBV) - Duck HBV [Strain 7/31/07]
 Hepatitis C virus (Human) (HCV) - Bovine Diarrhea Virus [Strain Oregon C24v-genotype 1]

Test Method Used:

Tests were conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of test for determining virucidal efficacy of disinfectants intended for use on dry inanimate surfaces.

Organic Soil Load:

Hepatitis B virus (HBV) 100% Duck Serum

Hepatitis C virus (HCV) 5% Horse Serum

Exposure Time:

3 minutes at 68°F

Results:

Virucidal against Hepatitis B and Hepatitis C viruses according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

HIV-1 (AIDS VIRUS) [Strain HTLV-III_B]

Test Method Used:

This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time for determining virucidal efficacy of disinfectants intended for use on dry inanimate surfaces.

Organic Soil Load:

5% Fetal Bovine Serum

Exposure Time:

30 seconds at 68°F

Results:

Virucidal against Human Immunodeficiency Virus Type 1 according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

NON-FOOD CONTACT SANITIZER ORGANISM EFFICACY

BACTERIAL ORGANISMS

Campylobacter jejuni [ATCC 29428]
Escherichia coli O157:H7 [ATCC 35150]
Escherichia coli [ATCC 11229]
Klebsiella pneumoniae [ATCC 4352]
Listeria monocytogenes [ATCC 19111]
 Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) [NARSA NRS384] (Genotype USA 300)
 Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) [NARSA NRS123] [Genotype USA 400]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC 10708]
Staphylococcus aureus [ATCC 6538]
Staphylococcus aureus (MRSA) [ATCC 33592]
Streptococcus pyogenes [ATCC 19615]

Test Method Used:

Modified ASTM Standard Test Method for Efficacy of Sanitizers Recommended For Non-Food Contact Surfaces

Organic Soil Load:

5% Fetal Bovine Serum

Exposure Time:

15 seconds at 68-71.6°F

Incubation:

48 hrs +/- 4 hrs at 95-98.6°F

Results:

Meets the efficacy data requirements set forth by the U.S. Environmental Protection Agency for non-food sanitizer label claims that a minimum of a 99.9% reduction of the test organism was achieved

TOXICITY

ACUTE ORAL TOXICITY OF SANI-CLOTH® AF3

Conclusion: A single dose of **Sani-Cloth AF3** solution was administered and observed for 14 days. No signs of toxicity were observed during the 14 day observation period of this study. Based on the results of this study, the acute oral toxicity LD50 of **Sani-Cloth AF3** was greater than 5gm/Kg of body weight.

ACUTE EYE IRRITATION OF SANI-CLOTH AF3

Conclusion: One eye of each subject was instilled with the undiluted solution, while the contralateral eye remained untreated and served as a control. Under the conditions of the test, **Sani-Cloth AF3** produced eye irritation clearing in 7 days or less.

ACUTE DERMAL TOXICITY OF SANI-CLOTH AF3

Conclusion: Following the single dermal administration, the subjects were observed for 14 days. Under the conditions of this test, the acute dermal LD50 of **Sani-Cloth AF3** was found to be greater than 5g/Kg of body weight.

ACUTE SKIN IRRITATION OF SANI-CLOTH AF3

Conclusion: This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing. The subjects were exposed to the undiluted solution for 72 hours. Under the conditions of the test, **Sani-Cloth AF3** produced minimal irritation in one subject clearing within 72 hours.

SKIN SENSITIZATION OF SANI-CLOTH AF3

Conclusion: This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing to determine the potential for **Sani-Cloth AF3** to produce sensitization after repeated topical applications. Based on the results of this test, **Sani-Cloth AF3** would not be considered a dermal sensitizing agent.

ACUTE INHALATION TOXICITY OF SANI-CLOTH AF3

Conclusion: This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing. The subjects were exposed to the aerosolized product for a four hour period. Based on the results of this study, the acute inhalation toxicity LD50 of **Sani-Cloth AF3** is greater than 2.57mg/L of air.