

Sani-Cloth® Bleach

GERMICIDAL DISPOSABLE WIPE



DIN 02450410

PRODUCT DESCRIPTION

DIN-Registered **Sani-Cloth®** Bleach wipes are designed to kill the most clinically relevant pathogens in healthcare. The stabilized 1:10 dilution of sodium hypochlorite is tested effective against 50 microorganisms, including 14 Multi-Drug Resistant Organisms (MDROs) with an overall contact time of four minutes. Ideal for disinfecting hard, non-porous surfaces in high risk areas endemic with Multi-Drug Resistant Organisms and *Clostridium difficile* spores.

CHEMICAL COMPOSITION

Active Ingredient

Sodium Hypochlorite.....	0.63%
Other Ingredients.....	99.37%
TOTAL.....	100.00%

(Does not include the weight of the wipe)

EFFICACY

CLOSTRIDIUM DIFFICILE EFFICACY

CLOSTRIDIUM DIFFICILE SPORES: *Clostridium difficile* spores [ATCC 43598]

Test Method Used: Modified ASTM E 2197-02, “Standard Quantitative Disk Carrier II Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides”, as specified by the U.S. EPA in “Guidance for the Efficacy Evaluation of Products with Sporicidal Claims Against *Clostridium difficile* spores” (February 5, 2009).

Organic Soil Load: None

Exposure Time: **4 minutes** at 73.4° – 75.2°F

Incubation: 7 days at 82.4° – 89.6°F

Results: Met the performance criterion of a minimum reduction in viable spores of 6 Log₁₀ for products with sporicidal claims against *Clostridium difficile*, in accordance with the U.S. EPA “Guidance for the Efficacy Evaluation of Products with the Sporicidal Claims Against *Clostridium difficile* spores” (February 5, 2009).

BACTERIAL ORGANISM EFFICACY

MULTI-DRUG RESISTANT BACTERIA: *Acinetobacter baumannii* Multi-Drug Resistant [ATCC 19606] [Effective against organisms resistant to Ampicillin, Cefazolin, Gentamicin, Trimethoprim / Sulfa and Intermediate resistance to Cefotaxime, Ceftriaxone and Piperacillin]
Enterobacter cloacae – NDM-1 positive [CDC 1000654]
Escherichia coli – NDM-1 positive [CDC 1001728]
 ESBL Resistant *Escherichia coli* [ATCC BAA-196]
 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]
Staphylococcus aureus Methicillin Resistant (MRSA) [ATCC 33592]
Streptococcus pneumoniae – Penicillin Resistant [ATCC 700677]
 Vancomycin Intermediate *Staphylococcus aureus* (VISA) [HIP 5836]
 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: **1 minute** at 68° – 69.8°F

Incubation: 2 – 8 days at 95° – 98.6°F

Results: No growth observed

TB: *Mycobacterium bovis* – BCG (TB)

Test Method Used: Modified AOAC Method for Pre-Saturated Towelettes for Hard Surface Disinfection to Determine Tuberculocidal Effectiveness

Organic Soil Load: 5% Horse Serum

Exposure Time: **2 minutes** at 68°F

Incubation: 90 days at 98.6°F

Results: No growth observed

BACTERIA: *Bordetella pertussis* [ATCC 12743]
Burkholderia cepacia [ATCC 25416]
Campylobacter jejuni [ATCC 29428]
Escherichia coli [ATCC 11229]

BACTERIA: *Klebsiella pneumoniae* [ATCC 4352]
Legionella pneumophila [ATCC 33153]
Listeria monocytogenes [ATCC 19117]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC 10708]
Serratia marcescens [ATCC 14756]
Staphylococcus aureus [ATCC 6538]
Streptococcus pyogenes [ATCC 12344]

Test Method Used: Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
 Organic Soil Load: 5% Fetal Bovine Serum
 Exposure Time: **1 minute** at 68°F
 Incubation: 2 – 5 days at 95° – 98.6°F
 Results: No growth observed.

VIRAL ORGANISM EFFICACY

ENVELOPED VIRUSES: Avian Influenza A H5N1 virus
 [Strain VNH5N1-PR8/CDC-RG CDC #2006719965]
 Cytomegalovirus (CMV) [ATCC VR-538]
 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 2 [ATCC VR-846]
 Adenoid 6 Strain Canine Parvovirus [ATCC VR-2017]
 Cornell Strain Hepatitis A virus (Human) (HAV) [Strain HM-175]
 Norovirus (Feline Calicivirus) [ATCC VR-782]
 Poliovirus type 1 [ATCC VR-1562] Chat Strain
 Rhinovirus type 37 [ATCC VR-1147], Strain 151-1
 Rotavirus [Strain WA]

Test Method Used: Tests were conducted according to U.S. EPA 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: **1 minute** at 68°F
 Results: Virucidal according to the criteria established by the U.S. EPA 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. EPA guidelines in effect at the time 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: **1 minute** at 68°F
 Results: Virucidal against Hepatitis B and Hepatitis C viruses according to the criteria established by the U.S. EPA for registration and labeling of a disinfectant product as a virucide.

HIV-1 (AIDS virus) [Strain HTLV-IIIB]

Test Method Used:	This test was conducted according to U.S. EPA 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:	1 minute at 68°F
Results:	Virucidal against Human Immunodeficiency Virus Type 1 according to the criteria established by the U.S. EPA for registration and labeling of a disinfectant product as a virucide.

PATHOGENIC FUNGI EFFICACY

YEAST ORGANISMS:	<i>Candida albicans</i> [ATCC 10231] <i>Aspergillus brasiliensis</i> [ATCC 16404] <i>Trichophyton mentagrophytes</i> [ATCC 9533]
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Test Method Used:	Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
Organic Soil Load:	5% Fetal Bovine Serum
Exposure Time:	4 minutes at 70° – 77°F
Incubation:	2 – 10 days at 77° – 86°F
Results:	No growth observed

TOXICITY

ACUTE ORAL TOXICITY

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

ACUTE EYE IRRITATION

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** Bleach wipes produced eye irritation clearing in 7 days or less.

ACUTE DERMAL TOXICITY

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

ACUTE SKIN IRRITATION

Conclusion: This test was conducted according to U.S. EPA guidelines in effect at the time of testing. The subjects were exposed to the undiluted solution for 4 hours. Under the conditions of the test, **Sani-Cloth** Bleach wipes produced minimal skin irritation.

SKIN SENSITIZATION

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

ACUTE INHALATION TOXICITY

Conclusion: This test was conducted according to U.S. EPA 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 LC50 of **Sani-Cloth** Bleach wipes is greater than 2.35 mg/L of air.