Technical Data Bulletin

Sani-Cloth® **Bleach**
GERMICIDAL DISPOSABLE WIPE

EPA Reg. No. 9480-8

Product Description

Sani-Cloth® Bleach Germicidal Disposable Wipe is a bleach-based disinfectant featuring a stabilized 1:10 dilution of sodium hypochlorite, designed to help protect patients, staff, and facilities by killing the most clinically relevant organisms in just four (4) minutes.

+ Proven efficacy against 52 microorganisms, including *Clostridioides difficile* spores, *Canida auris*, and 14 Multi-Drug Resistant Organisms (MDROs) such as MRSA and VRE.
+ Powerful bleach formula ideal for use in environments where controlling the spread of infection is critical.
+ Designed to be compatible with hard nonporous surfaces and equipment made of plastic, **Formica**® laminate, glass and more.*

Chemical Composition

Active Ingredient:

Sodium Hypochlorite	0.63%
Other Ingredients	99.37%
TOTAL	100.00%

* Refer to device manufacturer's instructions for use prior to use; Formica® is a registered trademark of The Diller Corporation.

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Efficacy

Bacterial Organism Efficacy

Multi-Drug Resistant Bacteria:

Acinetobacter baumannii - Multi-Drug Resistant (MDR) [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:	Pre-Saturated Towelette 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]
Escherichia coli O157:H7 [ATCC 35150]
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

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Viral Efficacy

Non-enveloped Virus:	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]
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
Test Method Used:	Tests were 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:	1 minute 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.
	Measles Virus [ATTC VR-24], Edmonston Strain
Test Method Used:	ASTM International E1053-20 Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces.
Organic Soil Load:	5.0% Newborn Calf Serum (NCS) in viral inoculum
Exposure Time:	4 minutes at 19-20°C
Incubation:	10–14 days at 34-38°C
Results:	Passed the Virucidal Hard-Surface Efficacy Test for a Pre-Saturated or Impregnated Towelette.
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 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. Environmental Protection Agency 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. 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:	1 minute 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.

Pathogenic Fungi Efficacy

Yeast Organisms	*Candida albicans* [ATCC 10231] *Aspergillus brasiliensis* [ATCC 16404] *Trichophyton mentagrophytes* [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
	Candida auris [AR-BANK# 0381]
Test Method Used:	QECD Quantitative Method for Evaluating the Efficacy of Liquid Antimicrobials against *Candida auris* on Hard, Non-Porous Surfaces
Organic Soil Load:	5% Fetal Bovine Serum
Exposure Time:	4 minutes at 20-24°C
Incubation:	72±4 hours at 28-32 °C
Results:	Kills a minimum of 99.999% or five logs of *Candida auris* on hard, non-porous surfaces

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 Log_{10} 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).

Toxicity Studies of **Sani-Cloth** Bleach Germicidal Disposable Wipe

Acute Oral
Conclusion: A single dose of **Sani-Cloth** Bleach 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 was greater than 5 g/Kg of body weight, classifed as Category IV.

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 produced eye irritation clearing in 7 days or less, classifed as Category III.

Acute Dermal
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 was found to be greater than 5 g/Kg of body weight, classified as Category IV.

Acute Skin Irritation
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 4 hours. Under the conditions of the test, **Sani-Cloth** Bleach produced minimal skin irritation, classified as Category IV.

Acute Inhalation
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 LC50 of **Sani-Cloth** Bleach is greater than 2.35 mg/L of air, classified as Category IV.

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

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