

Technical Data Bulletin

Sani-Cloth® Prime GERMICIDAL DISPOSABLE WIPE



EPA Reg. No. 9480-12

Product Description

Sani-Cloth® Prime Germicidal Disposable Wipe is a next-generation disinfectant powered by a proprietary blend of quaternary ammonium, isopropyl alcohol, and ethanol, that helps protect your patients, staff, and facility in just one (1) minute.

- + Proven efficacy against 56 microorganisms, including *Candida auris* and 17 Multi-Drug Resistant Organisms like MRSA, CRE, and VRE, within a one (1) minute contact time.
- + Fast acting disinfectants recommended for use in healthcare environment where the control of hazards of cross-contamination between treated surfaces is required.
- + Designed to be compatible with hard nonporous surfaces and equipment made of plastic, **Formica®** laminate, glass and more.*

Chemical Composition

Active Ingredients:

Didecyl Dimethyl Ammonium Chloride	0.61%
Ethyl Alcohol	27.30%
Isopropyl Alcohol	28.70%
Other Ingredients	43.39%
TOTAL	100.00%

Each cloth is saturated with 6,100 parts per million of active quaternary ammonium chlorides.

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



Efficacy

Bacterial Organism Efficacy

Multi-Drug Resistant Bacteria:

Acinetobacter baumannii – Multidrug Resistant (MDR) [ATCC 19606]
 Carbapenem Resistant – *Klebsiella pneumoniae* (CRKP) [ATCC BAA-1705]
 Carbapenem Resistant – *Escherichia coli* [CDC 81371]
 ESBL Positive *Klebsiella pneumoniae* [ATCC 700603]
 ESBL Positive *Escherichia coli* [ATCC BAA-196]
 Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33592]
 Multidrug Resistant (MDR) *Klebsiella pneumoniae*-KPC-2 positive [ST258] [CDC 2008030]
 Metallo-beta lactamase (MBL) positive *Pseudomonas aeruginosa* [CDC 2012059]
 Community Acquired Methicillin Resistant *Staphylococcus aureus* [CA-MRSA Genotype USA 300] [NRS 384]
 Community Acquired Methicillin Resistant *Staphylococcus aureus* [CA-MRSA Genotype USA 400] [NRS 123]
 NDM-1 Positive *Enterobacter cloacae* [CDC 1000654]
 NDM1 Positive *Escherichia coli* [CDC 1001728]
 NDM1 Positive *Klebsiella pneumoniae* [CDC 1000527]
Streptococcus pneumoniae – Penicillin Resistant [ATCC 700677]
 Vancomycin Intermediate Resistant *Staphylococcus aureus* (VISA) [HIP 5836]
 Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51575]
 Vancomycin Resistant *Staphylococcus aureus* (VRSA) [VRS1]
 Pre-Saturated Towelette Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
 Organic Soil Load: 5% fetal bovine serum
 Exposure Time: 1 minute
 Incubation: 46-50 hours at 25-37°C
 Results: No growth observed

Bacteria:

Bordetella pertussis [ATCC 12743]
Legionella pneumophila [ATCC 33153]
Campylobacter jejuni [ATCC 29428]
Burkholderia cepacia [ATCC 25416]
Enterobacter aerogenes [ATCC 13048]
Escherichia coli (*E. coli*) [ATCC 11229]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC10708]*
Staphylococcus aureus [ATCC 6538]*
Shigella dysenteriae [ATCC 11835]
Streptococcus pyogenes [ATCC 12344]
Streptococcus pneumoniae [ATCC 6305]
Klebsiella pneumoniae [ATCC 4352]
Escherichia coli (*E. coli*) O157:H7 [ATCC 35150]
Listeria monocytogenes [ATCC 19117]
Proteus vulgaris [ATCC 9920]

Pre-Saturated Towelette Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
 Organic Soil Load: 5% fetal bovine serum
 Exposure Time: 1 minute
 Incubation: 2-3 days at 35-37 °C
 Results: No growth observed

Mycobacterium Bovis - BCG (TB):

Test Method Used:

Mycobacterium bovis BCG (Tuberculosis) (TB) [Organon Teknika] [ATCC 35743]
 AOAC Method 965.12 Tuberculocidal Activity of Disinfectants (2012)
 (Modified for Pre-saturated Towelettes)

Organic Soil Load:

5% concentration horse Serum

Exposure Time:

1 minute at 21°C

Incubation:

90 days at 35-37°C

Results:

No growth observed

Viral Efficacy

Non-enveloped Virus (3 minute contact time):

Test Method Used: Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test
 Organic soil load: 5% serum in virus inoculum
 Incubation: 7-9 days at 36±2°C and 5±3% CO₂
 Exposure Time: 3 minutes
 Results: Virucidal according to the criteria established by the 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.

Non-enveloped Viruses (1 minute contact time):

Murine Norovirus [Strain: MNV-G] [Yale University]
 Adenovirus type 5 [ATCC VR-5]*
 Enterovirus EV-D68 [ATCC VR-561]
 Rhinovirus type 1A [ATCC VR-1559] [Strain 2060]*
 Rotavirus (Strain WA)
 Test Method Used: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surface
 Pre-Saturated or Impregnated Towelette Virucidal Efficacy Test
 Organic soil load: 5% fetal bovine serum
 Incubation: 7-10 days at 34-38°C
 Exposure Time: 1 minute at room temperature (20.0 +/- 1°C)
 Results: Virucidal according to the criteria established by the 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.

Enveloped Viruses:

Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) USA-WA1/2020
 Avian Influenza A (H5N1) virus [CDC 2006719965] [Strain VNHN51-PR8/CDC-RG]
 Avian Influenza A (H7N9) virus [CDC-2013759189]
 Cytomegalovirus [ATCC VR-538] [Strain AD-169]*
 Herpes Simplex virus type 1 [ATCC VR-733] [Strain (F-1)]
 Herpes Simplex virus type 2 [ATCC VR-734] [Strain G]
 Human Coronavirus [Strain 229E] [ATCC VR-740]
 Influenza A virus (H3N2) [ATCC VR-544]
 Influenza B virus [ATCC VR-823]
 Respiratory Syncytial virus (RSV) [ATCC VR-26], Strain Long
 Vaccinia virus (Strain WR) [ATCC VR-119]
 Test Method Used: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
 Organic Soil Load: 5% fetal bovine serum
 Exposure Time: 1 minute
 Incubation: 7-10 days
 *28 days
 Results: Virucidal according to the criteria established by the 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.

Pathogenic Fungi

Test Method Used: Fungicidal Germicidal Spray Method
 Organic Soil Load: 5% fetal bovine serum
 Exposure Time: 1 minute at 18-25°C
 Incubation: 46-50 hours at 25-30°C
 Results: No growth observed

Trichophyton interdigitale (Formerly known as *Trichophyton mentagrophytes*) [ATCC 9533]
 Test Method Used: Pre-Saturated Towelette Modified AOAC Fungicidal Germicidal Spray Test
 Organic Soil Load: 5% fetal bovine serum
 Exposure Time: 1 minute at 18-25°C
 Incubation: 10 days at 36-38°C
 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: 1 minute at 18-25°C
Incubation: 120±4 hours at 29-31 °C
Results: Kills a minimum of 99.999% or five logs of *Candida auris* on hard, non-porous surfaces

Bloodborne Pathogens: Human Immunodeficiency virus type 1 (HIV) (AIDS Virus), Strain HTLV-III_B
Test Method Used: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Organic Soil Load: 5% fetal bovine serum
Exposure Time: 1 minute
Incubation: 10-14 days at 36-38 °C
Results: The results indicate complete inactivation of Human Immunodeficiency Virus type 1 virus under these test conditions as required by the U.S. EPA and Health Canada.

Test Method Used: Duck Hepatitis B Virus as a surrogate for Human Hepatitis B Virus
Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Organic Soil Load: Whole duck serum (100% duck serum) with an additional 5% fetal bovine serum
Exposure Time: 1 minute
Incubation: 10 days at 36-38 °C
Results: The results indicate complete inactivation of Duck Hepatitis B virus under these test conditions as required by the U.S. EPA and Health Canada.

Test Method Used: Bovine Viral Diarrhea virus as a surrogate for Human Hepatitis C virus
Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Organic Soil Load: 5% horse serum
Exposure Time: 1 minute
Incubation: 7 days at 36-38 °C
Results: The results indicate complete inactivation of Bovine Viral Diarrhea virus under these test conditions as required by the U.S. EPA and Health Canada.

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

Acute Oral

Conclusion: A single-dose of **Sani-Cloth Prime** Germicidal Disposable Wipe solution was administered and observed for 14 days. Based on the results of this study, **Sani-Cloth Prime** Germicidal Disposable Wipe has an acute oral toxicity LD50 greater than 2 g/kg of body weight, classified as Toxicity Category III.

Primary Eye Irritation

Conclusion: All eye irritation cleared within the timed observation period resulting in no permanent eye damage. In accordance with the OPPTS/OECD Guidelines, **Sani-Cloth Prime** Germicidal Disposable Wipe would be classified as Toxicity Category II in unwashed eyes.

Acute Dermal

Conclusion: Following the single dermal administration, the subjects were observed for 14 days. Under the conditions of this test, the acute dermal LD50 was found to be greater than 5 g/kg of body weight, classified as Toxicity Category IV.

Primary Dermal

Conclusion: Following a single dermal administration, the subjects were observed for 14 days. All irritation cleared within the observation period, and the product met the requirements for Toxicity Category IV classification.

Acute Inhalation

Conclusion: Following four hours of exposure to the aerosolized product, the subjects were observed for 14 days. The inhalation LC50 was observed to be greater than 0.55 mg/L over the four hour period, classified as Toxicity Category III.

Skin Sensitization

Conclusion: Incidence of grade 1 response or greater to primary challenge dose within the test group was not significantly greater than the naïve group, indicating that sensitization had not been induced.