

Technical Data Bulletin



EPA Reg. No. 9480-16

Product Description

With **Sani-HyPerCide**[®] Germicidal Disposable Wipes, you can help protect your patients and equipment. This Hydrogen Peroxide ready to use disinfectant is formulated to provide effective defense against HAI causing microorganisms, including *Clostridioides difficile** without compromising compatibility.**

Chemical Composition

Active Ingredients:

Hydrogen Peroxide.....	4.04%
Other Ingredients.....	95.96%
TOTAL.....	100.00%



Efficacy

Clostridioides Difficile Spores*: *Clostridioides 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 Sporocidal Activities of Liquid Chemical Germicides, as specified by the U.S. EPA in Guidance for the Efficacy Evaluation of Products with Sporocidal Claims against *Clostridioides difficile* spores* (February 5, 2009).
 Organic Soil Load: EPA three-part soil load
 Exposure Time: 5 minutes at 73.4° - 75.2°F
 Incubation: 5 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 sporocidal claims against *Clostridioides difficile* spores*, in accordance with the U. S. EPA Guidance for the Efficacy Evaluation of Products with the Sporocidal Claims Against *Clostridioides difficile* spores* (February 5, 2009).

Multi-Drug Resistant Bacteria: *Acinetobacter baumannii* – Multidrug Resistant (MDR) [ATCC 19606]
 Carbapenem Resistant – *Klebsiella pneumoniae* (CRKP) [ATCC BAA-1705]*
 ESBL Positive *Enterobacter cloacae* [CDC 1000654]
 NDM1 Positive *Escherichia coli* [ATCC BAA-196]
 Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33592]
 Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51575]
 Test Method Used: AOAC Germicidal Spray Method for Hard Surface Disinfection
*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: *Staphylococcus aureus* [ATCC 6538]*
Pseudomonas aeruginosa [ATCC 15442]*
Salmonella enterica [ATCC 10708]*
 Test Method Used: AOAC Germicidal Spray Method for Hard Surface Disinfection
*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

Non-Enveloped Viruses: Norovirus - Utilizing Feline Calicivirus [ATCC VR-782] [F-9 Strain] as a Surrogate for Norovirus
 Adenovirus type 5 [ATCC VR-5] [Strain Adenoid 75]*
 Rhinovirus type 1a [ATCC VR-1559] [Strain 2060]*
 Rotavirus [ATCC VR-2018] (Strain WA)
 Test Method Used: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surface
*Pre-Saturated 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:	Herpes Simplex virus type 2 [ATCC VR-734] [Strain G] Influenza A virus (H3N2) / Strain Hong Kong [ATCC VR-544] Respiratory Syncytial virus (RSV) [ATCC VR-26], Strain Long
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
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.
Bloodborne Pathogens:	Hepatitis B virus (HBV) Duck Hepatitis B Virus as a surrogate for Human Hepatitis B Virus
Test Method Used:	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.
Bloodborne Pathogens:	Hepatitis C virus (HCV) Bovine Viral Diarrhea virus as a surrogate for Human Hepatitis C virus
Test Method Used:	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.
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.
Mycobacterium bovis–BCG (TB):	<i>Mycobacterium bovis BCG</i> (Tuberculosis) (TB) [Organon Teknika] [ATCC 35743]
Test Method Used:	AOAC Method 965.12 Tuberculocidal Activity of Disinfectants (2012) (Spray and 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

Pathogenic Fungi:	<i>Candida albicans</i> [ATCC 10231]
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
Pathogenic Fungi:	<i>Candida auris</i> AR-BANK#0381 from CDC
Test Method Used:	OECD Quantitative Method for Evaluating the Efficacy of Liquid Antimicrobials against <i>Candida auris</i> on Hard, Non-Porous Surfaces, Wipes and Towelettes
Organic Soil Load:	5% fetal bovine serum
Exposure Time:	1 minute at 21°C
Incubation:	116-124 hours at 29-31°C
Results:	Met the performance criterion of a minimum reduction in viable cells of 5 Log ₁₀ in accordance with the U.S. EPA guidance for the Efficacy Evaluation of Products for Claims against <i>Candida auris</i> .
Pathogenic Fungi:	<i>Trichophyton interdigitale</i> [[Formerly known as] [(Tested as) <i>Trichophyton mentagrophytes</i>]] [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

Toxoxiity

Acute Inhalation

Based on the inhalation test results, **Sani-HyPerCide** disinfectant has been classified as Toxicity Category IV for acute inhalation.

Acute Oral Toxicity

Based on the results of this study, **Sani-HyPerCide** disinfectant has been classified as Toxicity Category IV for acute oral toxicity.

Acute Eye Irritation

Based on the results of this study, **Sani-HyPerCide** disinfectant produced eye irritation that indicates the product would be classified as Toxicity Category III for acute eye irritation.

Acute Dermal Toxicity

Based on the results of this study, **Sani-HyPerCide** disinfectant has been classified as Toxicity Category IV for dermal toxicity.

Acute Dermal Irritation

Based on the results of primary skin irritation study, **Sani-HyPerCide** disinfectant has been classified as Toxicity Category IV for dermal effects.

Dermal Sensitization

Based upon the sensitization test results, **Sani-HyPerCide** disinfectant would not be considered a dermal sensitizing agent.

* *Clostridioides difficile* spores formerly known as *Clostridium difficile* spores.

** Refer to device manufacturer's instructions for use.