

Sani-HyPerCide™

GERMICIDAL SPRAY

EPA Reg. No. 9480-14



PRODUCT DESCRIPTION

With **Sani-HyPerCide™** Germicidal Spray, you have the power to protect your patients and equipment. It is the only Hydrogen Peroxide sporicidal ready to use spray designed to provide powerful protection against HAI causing microorganisms, including *Clostridium difficile* to help standardize your disinfection protocols without compromising compatibility.

CHEMICAL COMPOSITION

Active Ingredients:

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

EFFICACY

CLOSTRIDIUM DIFFICILE SPORES:

Test Method Used:

Clostridioides difficile spores formerly known as *Clostridium difficile* spores [ATCC 43598] 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 *Clostridioides difficile* spores formerly known as *Clostridium 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 sporicidal claims against *Clostridioides difficile* spores formerly known as *Clostridium difficile*, in accordance with the U. S. EPA Guidance for the Efficacy Evaluation of Products with the Sporicidal Claims Against *Clostridioides difficile* spores formerly known as *Clostridium difficile* spores (February 5, 2009).

MULTI-DRUG RESISTANT BACTERIA:

Test Method Used:

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]
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:

Test Method Used:

Staphylococcus aureus [ATCC 6538]*
Pseudomonas aeruginosa [ATCC 15442]*
Salmonella enterica [ATCC 10708]*
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:

Test Method Used:

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)

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.

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):

Mycobacterium bovis BCG (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:

Candida albicans [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

Trichophyton interdigitale
 [[(Formerly known as) [(Tested 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

TOXICITY

ACUTE INHALATION

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

ACUTE ORAL TOXICITY

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

ACUTE EYE IRRITATION

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

ACUTE DERMAL IRRITATION

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

DERMAL SENSITIZATION

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