

Technical Data Bulletin



EPA Reg. No. 9480-17

Product Description

Sani-HP1™ Germicidal Disposable Wipe is an innovative disinfectant powered by a hydrogen-peroxide based formula, designed to deliver fast¹ and effective disinfection in just one (1) minute.²

- + Proven efficacy against a wide range of pathogens, including multi-drug resistant organisms, enveloped and non-enveloped viruses, and fungi, all within a one (1) minute contact time.³
- + Powered by PDI's proprietary **Hydroguard Technology™** to enhance material compatibility on hard, non-porous surfaces and sensitive healthcare equipment.⁴
- + Non-irritating with no PPE required (Category IV Safety Profile).³

Chemical Composition

Active Ingredients:

Hydrogen Peroxide	0.58%
Other Ingredients	99.42%
TOTAL	100.00%

¹As compared to surface disinfectants that require longer than 1 minute contact time. ²On hard, nonporous surfaces. ³See Technical Data Bulletin for a complete list of micro-organisms and toxicology results. ⁴Refer to device manufacturer's instructions for use prior to use.

Efficacy

Bacterial Organism Efficacy

Multi-Drug Resistant Bacteria:

Multi-Drug Resistant *Acinetobacter baumannii* (MDR) [ATCC BAA-1605]
 New Delhi metallo-beta-lactamase *Enterobacter cloacae* (NMD-1) [ATCC BAA-2468]
 Multi-Drug Resistant *Enterococcus faecium* [ATCC 51559]
 Extended spectrum β - lactamase *Escherichia coli* (ESBL) [ATCC BAA-196]
 New Delhi metallo-beta-lactamase *Escherichia coli* (NDM-1) [ATCC BAA-2469]
 Multi-Drug Resistant *Klebsiella aerogenes* [ATCC BAA-2356]
 Carbapenem-Resistant *Klebsiella pneumoniae* (CRKP) [ATCC BAA-1705]
 New Delhi metallo-beta-lactamase *Klebsiella pneumoniae* (NDM-1) [ATCC BAA-2146]
 Metallo- β -lactamase producing *Pseudomonas aeruginosa* [CDC 2012059 (AR-0230)]
 Penicillin-Resistant *Streptococcus pneumoniae* (PRSP) [ATCC 700677]

Test Method Used:

Pre-Saturated Towelette Modified AOAC Germicidal Spray Method for Hard Surface Disinfection

Organic Soil Load:

5% Fetal Bovine Serum (under 5% CO₂ for PRSP)

Exposure Time:

1 minute

Incubation:

46-50 hours at 20-37°C

Results:

No growth observed

Antibiotic Resistant Bacteria:

Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51575]
 Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33591]
 Vancomycin-Resistant *Staphylococcus aureus* (VRSA) [NR-46410]
 Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) [ATCC 700565]

Test Method Used:

Pre-Saturated Towelette Modified AOAC Germicidal Spray Method for Hard Surface Disinfection

Organic Soil Load:

5% Fetal Bovine Serum (under 5% CO₂ for PRSP)

Exposure Time:

1 minute

Incubation:

46-50 hours at 20-37°C

Results:

No growth observed

Bacteria:

Bordetella pertussis [ATCC BAA-589]
Burkholderia cepacia [ATCC 25416]
Campylobacter jejuni [ATCC 29428]
Citrobacter freundii [ATCC 8090]
Escherichia coli O157:H7 [ATCC 35150]
Haemophilus influenzae [ATCC 19418]
Listeria monocytogenes [ATCC 19117]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC 10708]
Serratia marcescens [ATCC 14756]
Shigella dysenteriae [ATCC 12180]
Staphylococcus aureus [ATCC 6538]
Stenotrophomonas maltophilia [ATCC 25596]
Streptococcus pyogenes [ATCC 19615]
Vibrio cholerae [ATCC 11623]

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

Incubation:

2-3 days at 35-37 °C

Results:

No growth observed

Mycobacterium Bovis - BCG (TB):

Mycobacterium bovis (BCG) (Tuberculosis) (TB) [ATCC 35743]

Test Method Used:

AOAC Method 965.12 Tuberculocidal Activity of Disinfectants (2012)
 (Modified for Pre-Saturated Towelettes)

Organic Soil Load:

5% Concentration Horse Serum + 0.2% Sodium Thiosulfate

Exposure Time:

1 minute

Incubation:

60-90 days at 35-37°C

Results:

No growth observed

Viral Efficacy

Non-Enveloped Viruses:

Adenovirus Type 7 [Strain: Gromen] [ATCC VR-7]
 Enterovirus (EV-D68) [Strain: Fermon] [ATCC VR-561]
 Feline Calicivirus (Surrogate for Human Norovirus) [Strain: F9] [ATCC VR-782]
 Hepatitis A Virus (HAV) [Strain: HM175/18f]
 Poliovirus Type 1 [Strain: Chat] [ATCC VR-1562]
 Rhinovirus Type 37 [Strain: 151-1] [ATCC VR-1607]
 Rotavirus [Strain: WA] [ATCC VR-2018]

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:

6-15 days at 34-38°C and 2-8% CO₂

Exposure Time:

1 minute

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:

Avian Influenza A Virus (H5N1) [Strain: NIBRG-14]
 Cytomegalovirus [Strain: Davis] [ATCC VR-807]
 Herpes Simplex Virus Type 1 [Strain: HF] [ATCC VR-260]
 Herpes Simplex Virus Type 2 [Strain: G] [ATCC VR-734]
 Human Coronavirus [Strain: 229E] [ATCC VR-740]
 Human Respiratory Syncytial Virus (RSV) [Strain: Long] [ATCC VR-26]
 Influenza A Virus (H1N1) [A/California/04/09]
 Influenza A Virus (H3N2) [A/Hong Kong/8/68]
 Influenza B Virus [B/Lee/40]
 Measles Virus [Strain: Edmonston] [ATCC VR-24]
 Middle East Respiratory Syndrome Coronavirus (MERS-CoV) [Strain: EMC/2012]
 Parainfluenza Virus Type 3 [Strain: C243] [ATCC VR-93]
 Severe Acute Respiratory Syndrome-related Coronavirus (SARS-CoV-2) [Strain: USA-WA1/2020]

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:

4-18 days at 34-38°C and 2-8% CO₂

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

Aspergillus fumigatus [ATCC 10894]

Test Method Used:

Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection

Organic Soil Load:

5% Fetal Bovine Serum

Exposure Time:

1 minute at 20°C

Incubation:

46-76 hours at 25-30°C

Results:

No growth observed

Candida albicans [ATCC 10231]

Test Method Used:

Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection

Organic Soil Load:

5% Fetal Bovine Serum

Exposure Time:

1 minute at 18-25°C

Incubation:

46-50 hours at 29-31°C

Results:

No growth observed

Candida auris [Drug-Resistant Strain]

Test Method Used: OECD 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

Nakaseomyces glabratus [ATCC 2001]

Test Method Used: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection
 Organic Soil Load: 5% Fetal Bovine Serum
 Exposure Time: 1 minute at 21°C
 Incubation: 48±2 hours at 25-30°C
 Results: No growth observed

Trichophyton interdigitale [ATCC 9533]

Test Method Used: Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection
 Organic Soil Load: 5% Fetal Bovine Serum
 Exposure Time: 1 minute at 20°C
 Incubation: 44-76 hours at 25-30°C
 Results: No growth observed

Bloodborne Pathogens:

Human Hepatitis B Virus (HBV) - Duck Hepatitis B Virus (as surrogate) [Strain: Grimaud]

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: 12 days at 34-38 °C and 2-8% CO₂
 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.

Hepatitis C Virus (HCV) - Bovine Viral Diarrhea Virus (as surrogate) [Strain: NADL]

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: 9 days at 34-38°C and 2-8% CO₂
 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 (HIV-1) (AIDS Virus) [Strain: 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 days at 34-38°C and 2-8% CO₂
 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.

Toxicity Studies of **Sani-HP1™** Germicidal Disposable Wipe

Acute Oral

Conclusion: A single-dose of **Sani-HP1** Germicidal Disposable Wipe solution was administered and observed for 14 days. Based on the results of this study, **Sani-HP1** Germicidal Disposable Wipe has an acute oral toxicity LD₅₀ greater than 5000mg/kg of body weight, classified as Toxicity Category IV according to criteria set forth in the U.S. Environmental Protection Agency (EPA) health test effects guidelines. The test article is not considered toxic according to the US Consumer Product Safety Commission (CPSC).

Primary Eye Irritation

Conclusion: **Sani-HP1** solution elicited no positive responses according to the criteria set forth in the U.S. Environmental Protection Agency (EPA) health test effects guidelines and is classified as Category IV.

Acute Dermal

Conclusion: The acute dermal LD₅₀ is greater than 5000mg/kg of body weight per the criteria set forth in the U.S. Environmental Protection Agency (EPA) health test effects guidelines. Therefore, **Sani-HP1** is classified as Category IV.

Primary Dermal

Conclusion: Following a single dermal administration, the subjects were observed for 14 days. Given the Primary Irritation Index (PII) was 0.0 and no erythema or edema was noted at 24, 48, and 72 hours post-exposure, in accordance with US EPA health effects test guidelines, **Sani-HP1** is considered non-irritating to skin and classified as Category IV.

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 2.04 mg/L over the four-hour period per the criteria set forth in the U.S. Environmental Protection Agency (EPA) health test effects guidelines and is classified as Category IV.

Skin Sensitization

Conclusion: There were no incidences of dermal reactions during the challenge phase for **Sani-HP1**. **Sani-HP1** is not considered a skin sensitizer per the US Environmental Protection Agency (EPA) health effects test guidelines.

