Technical Data Bulletin

Sani-HP1™
GERMICIDAL WIPE

EPA Reg. No. 9480-17
Pending Full Regulatory Approval*

Product Description

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

+ Proven efficacy against a wide range of pathogens, including multi-drug resistant organsisms, 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 compatability 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%

*State regulatory approvals are in progress.
Product availability may vary—contact your PDI rep for availability in your state.

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

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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 *Klebsiella pneumoniae* (NDM-1) [ATCC BAA-2146]
Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51575]
Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33591]

Test Method Used:	Pre-Saturated Towelette Modified AOAC Germicidal Spray Method for Hard Surface Disinfection
Organic Soil Load:	5% Fetal Bovine Serum (under 5% CO_2 for PRSP)
Exposure Time:	1 minute
Incubation:	46-50 hours at 20-37°C
Results:	No growth observed

Bacteria:

Pseudomonas aeruginosa [ATCC 15442]
Staphylococcus aureus [ATCC 6538]

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 35-37ºC
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]

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% CO_2
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:

Influenza A Virus (H1N1) [A/California/04/09]
Influenza B Virus [B/Lee/40]
Human Respiratory Syncytial Virus (RSV) [Strain: Long] [ATCC VR-26]
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% CO_2
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.

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Pathogenic Fungi	*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
	Trichophyton interdigitale [ATCC 9533]
Test Method Used:	Fungicidal Germicidal Spray Method
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 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% CO_2
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.
	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% CO_2
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% CO_2
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.

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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 LD_{50} 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 LD_{50} 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 LC_{50} 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.

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