Germicidal Disposable Cloth

TOXICITY

ACUTE ORAL TOXICITY OF SANI-CLOTH® AF

Conclusion: A single dose of Sani-Cloth® AF solution was administered and observed for 14 days. No signs of toxicity were observed during the 14 day observation period of this study. Based on the results of this study, the acute oral toxicity LD50 of Sani-Cloth® AF was greater than 5g/Kg of body weight.

ACUTE EYE IRRITATION OF SANI-CLOTH® AF

Conclusion: One eye of each subject was instilled with the undiluted solution, while the contralateral eye remained untreated and served as a control. Under the conditions of the test, Sani-Cloth® AF produced eye irritation clearing in 7 days or less.

ACUTE DERMAL TOXICITY OF SANI-CLOTH® AF

Conclusion: Following the single dermal administration, the subjects were observed for 14 days. Under the conditions of this test, the acute dermal LD50 of Sani-Cloth® AF was found to be greater than 5g/Kg of body weight.

ACUTE SKIN IRRITATION OF SANI-CLOTH® AF

Conclusion: This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing. The subjects were exposed to the undiluted solution for 72 hours. Under the conditions of the test, Sani-Cloth® AF produced mild or slight irritation at 72 hours.

SKIN SENSITIZATION OF SANI-CLOTH® AF

Conclusion: This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing to determine the potential for Sani-Cloth® AF to produce sensitization after repeated topical applications. Based on the results of this test, Sani-Cloth® AF would not be considered a dermal sensitizing agent.

ACUTE INHALATION TOXICITY OF SANI-CLOTH® AF

Conclusion: This test was conducted according to U.S. Environmental Protection Agency guidelines in effect at the time of testing. The subjects were exposed to the aerosolized product for a four hour period. Based on the results of this study, the acute inhalation toxicity LD50 of Sani-Cloth AF is greater than 2.1mg/L of air.
**PRODUCT DESCRIPTION**

Sani-Cloth® AF is a non-woven, disposable cloth, pre-saturated with a quaternary disinfectant cleaner. Recommended for use in hospitals and critical care areas where control of the hazards of cross contamination between treated surfaces is of prime importance. Use on hard, nonporous surfaces and equipment. Disinfects in just 3 minutes.

**CHEMICAL COMPOSITION**

Active ingredients:
- n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides .........................................................0.14%
- n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides .....................................0.14%
- Other ingredients .....................................................................................................................................................99.72%
- Total (Does not include the weight of the cloth)............................................................................................................100.00%

**EFFICACY**

**BACTERIAL ORGANISM EFFICACY**

**ORGANISMS:**
- Acinetobacter baumanii, Multi-Drug Resistant (ATCC 19606)
- Campylobacter jejuni (ATCC 29429)
- Vancomycin Resistant Enterococcus faecalis (VRE) (ATCC 51575)
- Escherichia coli (E. coli) (ATCC 11229)
- Escherichia coli (E. coli) O157:H7 (ATCC 35158)
- ESBL Producing Escherichia coli (E. coli) (ATCC BAA-196)
- Klebsiella pneumoniae (ATCC 4352)
- Listeria monocytogenes (ATCC 19111)
- Community Acquired Methicillin Resistant Staphylococcus aureus - CA-MRSA (NARSA NRS134) (Genotype USA 100)
- Community Acquired Methicillin Resistant Staphylococcus aureus - (CA-MRSA) (NARSA NRS112) (Genotype USA 400)
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (Salmonella) (ATCC 10708)
- Staphylococcus aureus (Staph) (ATCC 6538)
- Methicillin Resistant Staphylococcus aureus - MRSA (ATCC 33592)
- Staphylococcus pyogenes (ATCC 19615)

Test Method Used: Modified AOAC Germicidal Spray Method for Hard Surface Disinfection

Organic Soil Load: 5% Fetal Bovine Serum

Exposure Time: 3 minutes at 68º - 68.9ºF

Results: Virucidal according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

**EFFICACY (continued)**

**VIRAL ORGANISM EFFICACY**

**ORGANISMS:**
- Avian Influenza A (H5N1), Strain VNH5N1-PR8/CDC-RG
- Human Coronavirus (ATCC VR-740, Strain 229E)
- Influenza A/Hong Kong Virus (ATCC VR-544)
- Pandemic 2009 Influenza A H1N1 Virus
- Respiratory Syncytial Virus (RSV) (ATCC VR-26, Strain Long)

Test Method Used: Tests were conducted according to U.S. Environmental Protection Agency guidelines in effect at the time for determining virucidal efficacy of disinfectants intended for use on dry inanimate surfaces.

Organic Soil Load: 5% Fetal Bovine Serum

Exposure Time: 3 minutes at 68º - 68.9ºF

Results: Virucidal against Hepatitis B and Hepatitis C viruses according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

**ORGANISMS:**
- Hepatitis B Virus (HBV), Duck Hepatitis B Virus Surrogate
- Hepatitis C Virus (HCV), Bovine Viral Diarrhea Virus Surrogate

Test Method Used: Tests were conducted according to U.S. Environmental Protection Agency guidelines in effect at the time for determining virucidal efficacy of disinfectants intended for use on dry inanimate surfaces.

Organic Soil Load: Hepatitis B Virus (HBV) 100% Duck Serum
- Hepatitis C Virus (HCV) 5% Horse Serum

Exposure Time: 3 minutes at 68ºF

Results: Virucidal against Human Immunodeficiency Virus Type 1 according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

**ORGANISMS:**
- HIV-1 AIDS Virus (ATCC HTLV-III-L)

Test Method Used: Tests were conducted according to U.S. Environmental Protection Agency guidelines in effect at the time for determining virucidal efficacy of disinfectants intended for use on dry inanimate surfaces.

Organic Soil Load: 5% Fetal Bovine Serum

Exposure Time: 30 seconds at 69.8ºF

Results: Virucidal against Human Immunodeficiency Virus Type 1 according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

**YEAST ORGANISM EFFICACY**

**ORGANISMS:**
- Candida albicans (ATCC 10233)

Test Method Used: Modified AOAC Germicidal Spray Method for Hard Surface Disinfection

Organic Soil Load: 5% Fetal Bovine Serum

Exposure Time: 3 minutes at 68.9ºF

Incubation: 3 days at 77 - 86º F

Results: No growth observed.
**PRODUCT DESCRIPTION**

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Total (Does not include the weight of the cloth): 100.00%

**EFFICACY**

**VIRAL ORGANISM EFFICACY**

**ORGANISMS:**
- Avian Influenza A (H5N1), Strain VNH5N1-PR8/CDC-RG
- Human Coronavirus (ATCC VR-740, Strain 229E)
- Influenza A/Hong Kong Virus (ATCC VR-544)
- Pandemic 2009 Influenza A/H1N1 Virus
- Respiratory Syncytial Virus (RSV) (ATCC VR-26, Strain Long)

Test Method Used: Tests were conducted according to U.S. Environmental Protection Agency guidelines in effect at the time for determining virucidal efficacy of disinfectants intended for use on dry inanimate surfaces.

Organic Soil Load: 5% Fetal Bovine Serum

Exposure Time: 3 minutes at 68° - 68.9°F

Results: Virucidal according to the criteria established by the U.S. Environmental Protection Agency for registration and labeling of a disinfectant product as a virucide.

**YEAST ORGANISM EFFICACY**

**ORGANISMS:**
- Candida albicans (ATCC 10231)

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Organic Soil Load: 5% Fetal Bovine Serum

Exposure Time: 3 minutes at 69.8°F

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**EFFICACY (continued)**

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- Vancomycin Resistant Enterococcus faecalis (VRE) (ATCC 51575)
- Escherichia coli (E. coli) (ATCC 11229)
- Escherichia coli (E. coli) O157:H7 (ATCC 35150)
- E. coli Production Escherichia coli (E. coli) (ATCC BAA-196)
- Klebsiella pneumoniae (ATCC 4432)
- Listeria monocytogenes (ATCC 19111)
- Community Acquired Methicillin Resistant Staphylococcus aureus - CA-MRSA (NARSA NR214) (Genotype USA 300)
- Community Acquired Methicillin Resistant Staphylococcus aureus - CA-MRSA (NARSA NR213) (Genotype USA 400)
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (Salmonella) (ATCC 10708)
- Staphylococcus aureus (Staph) (ATCC 6538)
- Methicillin Resistant Staphylococcus aureus - MRSA (ATCC 33592)
- Staphylococcus pneumoniae (ATCC 19615)

Test Method Used: Modified AOAC Germicidal Spray Method for Hard Surface Disinfection

Organic Soil Load: 5% Fetal Bovine Serum

Exposure Time: 3 minutes @ 68 - 69.8°F

Incubation: 2 – 5 days @ 95 - 98.6°F

Results: No growth observed.
TOXICITY

ACUTE ORAL TOXICITY OF SANI-CLOTH® AF

Conclusion: A single dose of Sani-Cloth® AF solution was administered and observed for 14 days. No signs of toxicity were observed during the 14 day observation period of this study. Based on the results of this study, the acute oral toxicity LD50 of Sani-Cloth® AF was greater than 5gm/Kg of body weight.

ACUTE EYE IRRITATION OF SANI-CLOTH® AF

Conclusion: One eye of each subject was instilled with the undiluted solution, while the contralateral eye remained untreated and served as a control. Under the conditions of the test, Sani-Cloth® AF produced eye irritation clearing in 7 days or less.

ACUTE DERMAL TOXICITY OF SANI-CLOTH® AF

Conclusion: Following the single dermal administration, the subjects were observed for 14 days. Under the conditions of this test, the acute dermal LD50 of Sani-Cloth® AF was found to be greater than 5g/Kg of body weight.

ACUTE SKIN IRRITATION OF SANI-CLOTH® AF

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