

AFFEX®

SUMMARY OF ANTIMICROBIAL ACTIVITY

Neutral Disinfectant Cleaner

Disinfectant, Virucide

Description

Neutral Disinfectant Cleaner Neutral Disinfectant & Detergent is a broad spectrum, neutral pH, hard surface disinfectant. When used as directed, this product will deliver effective biocidal action against bacteria, fungi, and viruses. This formulation is a blend of a premium active ingredients and inerts: surfactants, chelates, and water. Biocidal performance is attained when this product is properly diluted at 1/2 oz. per gallon or 1:256. **Neutral Disinfectant Cleaner** can be used to disinfect a wide variety of hard surfaces such as floors, walls, and countertops in hospitals, households, and institutions. Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)

Regulatory Summary

Physical Properties

EPA Registration No.	10324-141-
Sub-registrant No.	8325
USDA Authorization	None
California Status	No
Canadian PCP#	None
Canadian Din #	None

pH of Concentrate	6.0 – 8.0
Specific Gravity @ 25°C	1.01
Pounds per gallon @ 25°C	8.38

Flash Point (PMCC)	>200°F
% Quat (mol. wt.360.5)	16.05-17.77
% Volatile	77-78

Summary of Antimicrobial Test Results

This product Neutral Disinfectant & Detergent is a "One-Step" Hospital Disinfectant, Virucide, Fungicide, Mildewstat, and Cleaner. Listed below, and in the following pages, is a summary of the Antimicrobial Claims and a review of the Antimicrobial Test Results.

Hospital Disinfection (at 1/2 ounce per gallon)

Claim: Disinfectant	Contact Time: 10 minutes	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: Testing is performed per the AOAC UDT/GST method (DIS/TSS-1). Sixty carriers are required on 3 separate lots, one of which must be > 60 days old against <i>Pseudomonas aeruginosa</i> , <i>Salmonella enterica</i> and <i>Staphylococcus aureus</i> . Killing of 59 out of 60 carriers is required (total carriers = 540).			

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
<i>Pseudomonas aeruginosa</i>	15442	660 ppm	400 ppm	60, 60, 60	0/60, 0/60, 1/60
<i>Staphylococcus aureus</i>	6538	660 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
<i>Salmonella enterica</i>	10708	660 ppm	400 ppm	60, 60, 60	1/60, 1/60, 0/60

Supplemental Organisms Testing is performed per the AOAC UDT/GST method. Ten carriers are required on 2 separate lots against each supplemental organism. Killing of 10 out of 10 carriers is required (total carriers = 20).

<i>Acinetobacter baumannii</i>	19003	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Acinetobacter lwoffii</i>	15309	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Acinetobacter lwoffii</i>	9957	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Bordetella bronchiseptica</i>	10580	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Citrobacter freundii</i>	8090	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Chlamydia psittaci</i>	ATCC-VR-125	600ppm	400ppm	10,10	0/10, 0/10
<i>Enterobacter aerogenes</i>	13048	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterobacter agglomerans</i>	27155	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterobacter cloacae</i>	23355	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterococcus faecalis</i>	19433	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterococcus faecalis</i> (Vancomycin Resistant) (VRE)	51299	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Enterococcus hirae</i>	10541	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Escherichia coli</i>	11229	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Escherichia coli</i> Spectrum B- Lactamase (ESBL)	BAA-196	660 ppm	400 ppm	10, 10	0/10, 0/10

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Escherichia coli 0111:H8	BAA-184	660 ppm	400 ppm	10, 10	0/10, 0/10
Escherichia coli Tetracycline Resistant	47041	660 ppm	400 ppm	10, 10	0/10, 0/10
Fusobacterium necrophorum	27852	660 ppm	400 ppm	10, 10	0/10, 0/10
Klebsiella oxytoca	13182	660 ppm	400 ppm	10, 10	0/10, 0/10
Klebsiella pneumoniae	13883	660 ppm	400 ppm	10, 10	0/10, 0/10
Listeria monocytogenes	19117	660 ppm	400 ppm	10, 10	0/10, 0/10
Micrococcus luteus	14452	660 ppm	400 ppm	10, 10	0/10, 0/10
Micrococcus luteus	4698	660 ppm	400 ppm	10, 10	0/10, 0/10
Pasteurella multocida	12947	660 ppm	400 ppm	10, 10	0/10, 0/10
Proteus vulgaris	13315	660 ppm	400 ppm	10, 10	0/10, 0/10
Proteus vulgaris	9920	660 ppm	400 ppm	10, 10	0/10, 0/10
Pseudomonas aeruginosa Tetracycline Resistant	27853	660 ppm	400 ppm	10, 10	0/10, 0/10
Pseudomonas cepacia	25416	660 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella enterica	23564	660 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella enterica	4931	660 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella enterica Serotype pullorum	19945	660 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella Typhi	6539	660 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella Typhimurium	23564	660 ppm	400 ppm	10, 10	0/10, 0/10
Serratia marcescens	14756	660 ppm	400 ppm	10, 10	0/10, 0/10
Serratia marcescens	9103	660 ppm	400 ppm	10, 10	0/10, 0/10
Shigella Flexneri	12022	660 ppm	400 ppm	10, 10	0/10, 0/10
Shigella Flexneri	9380	660 ppm	400 ppm	10, 10	0/10, 0/10
Shigella Sonnei	25931	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus	14154	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus	25923	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus sub species aureus	33586	660 ppm	400 ppm	10, 10	0/10, 0/10

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Staphylococcus aureus, Methicillin Resistant (MRSA)	33592	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus Community Associated Methicillin-Resistant (CA-MRSA)	NRS123 USA300	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus Community Associated Methicillin-Resistant (CA-MRSA)	NRS384 USA400	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus Vancomycin Intermediate Resistant (VISA)	5836	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus epidermidis	14990	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus epidermidis Antibiotic Resistant	51625	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus haemolyticus	29970	660 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus agalactiae	13813	660 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus mutans	25175	660 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus pneumonia, Penicillin Resistant	51915	660 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus pyogenes	19615	660 ppm	400 ppm	10, 10	0/10, 0/10
Vibrio cholera	11623	660 ppm	400 ppm	10, 10	0/10, 0/10
Yersinia enterocolitica	23715	660 ppm	400 ppm	10, 10	0/10, 0/10

Conclusion: All lots of this product effectively killed the above listed bacteria as specified in the test performance standards. This product meets EPA requirements for hard surface disinfectant claims in hospital and medical environments when diluted to 660 ppm active concentration in 400 ppm synthetic hard water, and in the presence of 5% organic soil.

Mold and Mildew Control (at 1/2 ounce per gallon)

Claim: Mildewstat	Contact Time: 10 minutes	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: Mildewstat (Mold and Mildew Control) - EPA – TSD 6-201 Mildewstat on Hard Surfaces			

Organism	ATCC#	Tile Number	Untreated after 7 days	Sample A after 7 days	Sample B after 7 days
Aspergillus niger	16404	1	Growth 90%	No Growth 0%	No Growth 0%
		2	Growth 70%	No Growth 0%	No Growth 0%
		3	Growth 90%	No Growth 0%	No Growth 0%
		4	Growth 80%	No Growth 0%	No Growth 0%
		5	Growth 80%	No Growth 0%	No Growth 0%
		6	Growth 90%	No Growth 0%	No Growth 0%
		7	Growth 80%	No Growth 0%	No Growth 0%
		8	Growth 70%	No Growth 0%	No Growth 0%

Conclusion: All lots of this product were effective against *Aspergillus niger* under the test conditions outlined in the EPA test performance standards described above. This product is an effective mildewstat for non-porous inanimate hard surfaces when diluted to 660 ppm active concentration in 400 ppm synthetic hard water and in the presence of 5% organic soil.

Fungicidal against (at 1/2 ounce per gallon)

Claim: Fungicide	Contact Time: 10 minutes	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: Testing is performed per the AOAC fungicidal method (DIS/TSS-6). Two separate lots are tested against <i>Trichophyton mentagrophytes</i> in a suspension test. Killing of all fungal spores in 10 minutes is required.			

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
<i>Trichophyton mentagrophytes</i>	9533	660 ppm	400 ppm	10, 10	0/10, 0/10
<i>Candida albicans</i>	10321	660 ppm	400 ppm	10, 10	0/10, 0/10

Conclusion: All lots of this product effectively killed *Trichophyton mentagrophytes* and *Candida albicans* as specified in the test performance standards. This product is an effective fungicide for non-porous inanimate hard surfaces when diluted to 660 ppm active concentration in 400 ppm synthetic hard water and in the presence of 5% organic soil.

Virucidal against (at 1/2 ounce per gallon)

Claim: Virucide	Contact Time: Varies	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: Testing is performed per EPA Guidance (DIS/TSS-7). Two separate lots are tested. Inactivation of virus must be demonstrated at all dilutions when no cytotoxicity is observed or at all dilutions above the cytotoxic level when it is observed. The data must demonstrate a 3-log reduction in viral titer for both lots.			

Organism	Dried Virus Control	Sample	Result	Log REduction
Avian Influenza A (H1N1) virus		6.75 Log ₁₀	≤ 0.5 Log ₁₀	≥ 6.25 Log ₁₀
Avian Influenza A (H3N2) virus	VR-2072	4.75 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.25 Log ₁₀
Avian Infectious Bronchitis virus	Beaudette IB42	6.42 Log ₁₀	≤ 0.5 Log ₁₀	≥ 5.92 Log ₁₀
Canine coronavirus	ATCC-VR-809	4.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.0 Log ₁₀
Canine Distemper virus	ATCC-VR-128	6.25 Log ₁₀	≤ 0.5 Log ₁₀	≥ 5.75 Log ₁₀
Chlamydia psittaci	ATCC-VR-125	7.25 Log ₁₀	≤ 0.5 Log ₁₀	≥ 6.75 Log ₁₀
Cytomegalovirus	ATCC-VR-538	4.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.0 Log ₁₀
Feline Picornavirus	ATCC VR-649	4.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.0 Log ₁₀
Hantavirus	(PHV)	6.23 Log ₁₀	≤ 1.5 Log ₁₀	≥ 4.73 Log ₁₀
Hepatitis B (HBV)	N/A	5.06 Log ₁₀	0.27 Log ₁₀	4.79 Log ₁₀
Hepatitis C (HCV)	N/A	6.21 Log ₁₀	0.24 Log ₁₀	5.97 Log ₁₀
Herpes Simplex Type 1 virus	ATCC VR-733	5.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 5.0 Log ₁₀
Herpes Simplex Type 2 virus	ATCC VR-734	6.0 Log ₁₀	≤ 0.5 Log ₁₀	≥ 5.5 Log ₁₀
Human Corona Virus	ATCC VR-740	4.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.0 Log ₁₀
HIV-1 (AIDS Virus)	HTLV-III _B	5.75 Log ₁₀	≤ 1.5 Log ₁₀	≥ 4.25 Log ₁₀
Infectious Bovine Rhinotracheitis virus	ATCC VRE-188	4.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.0 Log ₁₀
Influenza A virus	ATCC VR-544	6.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 6.0 Log ₁₀
Influenza A (H1N1) virus	ATCC VR-1469	5.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 5.0 Log ₁₀
Pseudorabies Virus	ATCC VR-135	6.25 Log ₁₀	≤ 0.5 Log ₁₀	≥ 5.75 Log ₁₀
Respiratory Syncytial virus	ATCC VR-26	4.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.0 Log ₁₀
SARS Associated Coronavirus	N/A	6.5 Log ₁₀	≤ 3.5 Log ₁₀	≥ 3.0 Log ₁₀
Swine Influenza A (H1N1) Virus	ATCC VR-333	5.5 Log ₁₀	≤ 0.5 Log ₁₀	≥ 5.0 Log ₁₀
Transmissible Gastroenteritis virus	N/A	4.75 Log ₁₀	≤ 0.5 Log ₁₀	≥ 4.25 Log ₁₀
Vaccinia virus	ATCC VR-119	6.75 Log ₁₀	≤ 0.5 Log ₁₀	≥ 6.25 Log ₁₀
Rabies virus	N/A	5.75 Log ₁₀	≤ 2.5 Log ₁₀	≥ 3.25 Log ₁₀

Conclusion: All lots of this product effectively inactivated the above listed viruses as specified in the test performance standards. This product meets EPA requirements for hard surface virucidal claims in hospital and medical environments when diluted to 660 ppm in 400 ppm A.O.A.C. synthetic hard water and in the presence of 5% organic soil.

Virucidal against (at 1/2 ounces per gallon)

Claim: Virucide	Contact Time: Varies	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: Testing is performed per EPA Guidance (DIS/TSS-7). Two separate lots are tested. Inactivation of virus must be demonstrated at all dilutions when no cytotoxicity is observed or at all dilutions above the cytotoxic level when it is observed. The data must demonstrate a 3-log reduction in viral titer for both lots.			

Organism	Dried Virus Control	Sample	Result	Log Reduction
Canine Parvovirus Type 2b	Nike Strain	7.5 Log ₁₀	≤ 3.5 Log ₁₀	≥ 4.0 Log ₁₀
Minute virus of Mice (Parvovirus)	N/A	7.5 Log ₁₀	≤ 3.5 Log ₁₀	≥ 4.0 Log ₁₀
Porcine Parvovirus	N/A	7.5 Log ₁₀	≤ 3.5 Log ₁₀	≥ 4.0 Log ₁₀

Conclusion: All lots of this product effectively inactivated the above listed viruses as specified in the test performance standards. This product meets EPA requirements for hard surface virucidal claims in hospital and medical environments when diluted to 660 ppm in 400 ppm A.O.A.C. synthetic hard water and in the presence of 5% organic soil.