

SUMMARY OF ANTIMICROBIAL ACTIVITY

ELEMENTS Neutral Disinfectant/Cleaner

Neutral Disinfectant & Detergent

Description

ELEMENTSTM Neutral Disinfectant/Cleaner 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 2 oz. per gallon or 1:64. ELEMENTSTM 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.

Regulatory Summary

USDA Authorization No. California Status Canadian PCP# Canadian Din # 0 47371131-8325 None

Physical Properties

pH of Concentrate	7.2-8.2
•	
Specific Gravity @ 25°C	0.99
Pounds per gallon @	8.25
25°C	

Flash Point (PMCC)	>200°F
% Quat (mol. wt.360.5) % Volatile	

(rev. 06/23/04 jcg)

Summary of Antimicrobial Test Results

ELEMENTS™ Neutral Disinfectant/Cleaner 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.

Claim:	Contact Time:	Organic Soil:	Water Conditions:		
Disinfectant	10 minutes	10 minutes 5% 400 ppm as C			
Test Method:	Official Method of the	Official Method of the AOAC, 14 Edition			
	Use Dilution Method	Use Dilution Method			

Organism	ATCC#	Use-Dilution	Hard Water	Replicates	Results
		Concentration	Condition		
Pseudomonas	15442	600 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
aeruginosa		(2.0 oz/gal)			
Staphylococcus aureus	6538	600 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
Salmonella choleraesuis	10708	600 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
Acinetobacter calcoaceticus	23055	600 ppm	400 ppm	10, 10	0/10, 0/10
Bordetella bronchiseptica	31427	600 ppm	400 ppm	10, 10	0/10, 0/10
Chlamydia	VR-854	600 ppm	400 ppm	10, 10	0/10, 0/10
psittaci					
Enterobacter aerogenes	13048	600 ppm	400 ppm	10, 10	0/10, 0/10
Enterobacter cloacae	23355	600 ppm	400 ppm	10, 10	0/10, 0/10
Enterococcus (Streptococcus) faecalis (Vancomycin Resistant) (VRE)	51299	600 ppm	400 ppm	10, 10	0/10, 0/10
Escherichia coli	11229	600 ppm	400 ppm	10, 10	0/10, 0/10
Escherichia coli ¹ (Clinical Isolate)	(Clinical Isolate)	600 ppm	400 ppm	10, 10	0/10, 0/10
Fusobacterium necrophorum	27852	600 ppm	400 ppm	10, 10	0/10, 0/10
Klebsiella pneumoniae 2	13883	600 ppm	400 ppm	10, 10	0/10, 0/10
Legionella pneumophila	33153	600 ppm	400 ppm	10, 10	0/10, 0/10
Listeria monocytogenes	15313	600 ppm	400 ppm	10, 10	0/10, 0/10

¹Resistant to the Antibiotics: Ampicillin, Carbenicillin, Kanamycin, and Tetracycline.

 $² Resistant \ to \ the \ Antibiotics: \ Ampicillin, Carbenicillin, Chloramphenicol, \ and \ Tetracycline \ .$

Summary of Antimicrobial Test Results - (Continued)

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Pasteurella multocida	7707	600 ppm	400 ppm	10, 10	0/10, 0/10
Proteus mirabilis	25933	600 ppm	400 ppm	10, 10	0/10, 0/10
Proteus vulgaris	13315	600 ppm	400 ppm	10, 10	0/10, 0/10
Pseudomonas aeruginosa ³	Clinical Isolate	600 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella enteritidis	13076	600 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella Typhi	6539	600 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella Typhimurium	14028	600 ppm	400 ppm	10, 10	0/10, 0/10
Serratia marcescens	8100	600 ppm	400 ppm	10, 10	0/10, 0/10
Shigella Flexneri	12022	600 ppm	400 ppm	10, 10	0/10, 0/10
Shigella Sonnei	9290	600 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus (MRSA)	33592	600 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus ⁵	Clinical Isolate	600 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus ⁶ (VISA)	CDC No. HIP- 5836	600 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus epidermidis ⁷	Clinical Isolate	600 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus (Enterococcus) faecalis	19433	600 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus (Enterococcus) faecalis	19433	600 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus pyogenes	19615	600 ppm	400 ppm	10, 10	0/10, 0/10

Conclusion: All lots of ELEMENTS[™] Neutral Disinfectant/Cleaner effectively killed the above listed bacteria as specified in the test performance standards. ELEMENTS[™] Neutral Disinfectant/Cleaner meets EPA requirements for hard surface disinfectant claims in hospital and medical environments when diluted to 600 ppm active concentration in 400 ppm synthetic hard water, and in the presence of 5% organic soil.

3Resistant to the Antibiotics: Amikacin, Ampicillin, Carbenicillin, Cefamandole, Cefazolin, Cefoxitin, Chloramphenicol, Kanamycin, and Tetracycline.

⁴ Resistant to Gentamicin and Methicillin

⁵ Resistant to the Antibiotics: Cefazolin, Clindamycin, Erythomycin, Gentamicin, Kanamycin, Methicillin, Penicillin, Tetracycline and Tobramycin

⁶ Reduced Susceptibility to Vancomycin

 $^{7\} Resistant\ to\ the\ Antibiotics:\ Cefazolin,\ Chloramphenicol,\ Clindamycin,\ Erythomycin,\ Gentamicin,\ Kanamycin,\ Methicillin,\ Penicillin,\ Tetracycline\ and\ Tobramycin$

⁸ Resistant to the Antibiotics: Cefazolin, Chloramphenicol, Clindamycin, Erythomycin, Gentamicin, Kanamycin, Methicillin, Penicillin, Tetracycline and Tobramycin

Summary of Antimicrobial Test Results - (Continued)

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

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Aspergillus niger	6275	600 ppm (2.0 oz/gal)	400 ppm	10, 10	0/10, 0/10

Conclusion: All lots of ELEMENTS™ Neutral Disinfectant/Cleaner were effective against Aspergillus niger under the test conditions outlined in the EPA test performance standards described above. ELEMENTS™ Neutral Disinfectant/Cleaner is an effective mildewstat for non-porous inanimate hard surfaces when diluted to 600 ppm active concentration in 400 ppm synthetic hard water and in the presence of 5% organic soil.

Claim:	Contact Time:	Organic Soil:	Water Conditions:	
Fungicide	10 minutes 5% 400 ppm as CaC		400 ppm as CaCO₃	
Test Method:	Official Method of Analysis of the AOAC			
	Fungicidal Test.			

Organism	ATCC#	Dilution	Replicates	Results			
					5 Min	10 Min	15 Min
Trichophyton mentagrophytes	9533	600 ppm (2 oz/gal)	4	0/4	+	0	0
Candida albicans	11651	600 ppm (2 oz/gal)	4	0/4	+	0	0

Conclusion: All lots of ELEMENTS™ Neutral Disinfectant/Cleaner effectively killed Trichophyton mentagrophytes and Candida albicans as specified in the test performance standards. ELEMENTS™ Neutral Disinfectant/Cleaner is an effective fungicide for non-porous inanimate hard surfaces when diluted to 600 ppm active concentration in 400 ppm synthetic hard water and in the presence of 5% organic soil.

Summary of Antimicrobial Test Results - (Continued)

Claim:	aim: Contact Time: O		Water Conditions:
Virucide	Varies	5%	400 ppm as CaCO₃
Test Method:	EPA Guidelines		

Organism	Source of Virus or ATCC#	Host System; Cytopathic Effect	Use-Dilution Concentration	Contact Time	Replicates	Reduction (Log 10) of Virus Titer
Adenovirus Type 4	ATCC VR-4 strain RI-67	H. Ep. #2 cells Cytopathic Effects	600 ppm (2.0 oz/gal)	10 Min.	8	5.5, 5.5
Herpes Simplex Type 1	HSV-1; ATCC VR-733	VERO cells; lytic cytopathic effect	600 ppm	10 Min.	8	>7.5, 7.5
Herpes Simplex Type 2	HSV-2; MS Strain	VERO cells; lytic cytopathic effect	600 ppm	10 Min.	8	>6.5,6.5
HIV-1 (AIDS Virus)	HTLV-IIIRF; NCI	MT2 cells; lytic cytopathic effect	600 ppm	4 Min.	8	>3.0, 3.0
Influenza A/ Hong Kong	ATCC 68-H3N2	MDCK cells; lytic cytopathic effect	600 ppm	10 Min.	8	>8.0, 8.0
Hepatitis B	Hepadnavirus Testing	Hepatitis (w/5% serum)	660 ppm (2 oz./gal)	10 min.	2,2	>4.7, >4.9
Hepatitis B	Hepadnavirus Testing	Hepatitis (w/5% serum)	660 ppm (2 oz./gal)	10 min.	2	>4.7
Hepatitis C	Hepadnavirus Testing	Hepatitis (w/5% serum)	660 ppm (2 oz./gal)	10 min.	2	>4.7
Rubella virus	Strain M-33	RK13 cells; cytopathic effect	600 ppm	10 Min.	8	>5.0, 5.0
Rabies virus	ATCC VR-138		600 ppm	10 Min.	8	4.5, 4.5
Respiratory Syncytial virus	ATCC VR-26		600 ppm	10 Min.	8	4.0, 4.5
Vaccinia	Strian IHD	VERO Cells; lytic cytopathic effect	600 ppm	10 Min.	8	>70, 7.0
Avian Infectious Bronchitis virus	ATCC VR-22		600 ppm	10 Min.	8	6.0, 6.25
Avian Polyomavirus	lab isolate		600 ppm	10 Min	8	4.0, 6.0
Canine Distemper virus	ATCC-VR-256		600 ppm	10 Min.	8	3.5, 3.5
Feline Leukemia Virus	ATCC VR-717 Strain FL-237		600 ppm	10 Min.	8	4.5, 4.75
Feline Picornavirus	ATCC VR-649		600 ppm	10 Min.	8	5.0, 5.0
Infectious Bovine Rhinotracheitis	ATCC VR-793		600 ppm	10 Min	8	8.0,8.0
Pseudorabies Virus	ATCC VR-135		600 ppm	10 Min.	8	5.5, 5.5
Transmissible Gastroenteritis	ATCC VR-763		600 ppm	10 Min.	8	3.5, 3.5

Conclusion: All lots of ELEMENTS™ Neutral Disinfectant/Cleaner effectively inactivated the above listed viruses as specified in the test performance standards. ELEMENTS™ Neutral Disinfectant/Cleaner 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.

Summary of Antimicrobial Efficacy - Etiology⁹

Pathogenic Microorganism	Description
Pseudomonas aeruginosa	Gram negative bacteria identified as a major cause of hospital acquired
	(nosocomial) infections. Causes wound infections (especially burn), meningitis,
0: 1.1	pneumonia and eye infections. Required for Hospital Disinfectants.
Staphylococcus aureus	Gram positive bacteria identified as a major cause of hospital acquired
	(nosocomial) infections. Colonizes food and secretes enterotoxins which cause
	food poisoning after ingestion. Causes wound infections, septicemia,
	endocarditis, meningitis, osteomylitis and pneumonia. Required for Hospital Disinfectants.
Salmonella choleraesuis	Gram negative bacteria associated with acute gastroenteritis and septicemia.
	Required for Hospital Disinfectants.
Acinetobacter calcoaceticus	Gram negative (spherical shape) bacteria. Occurs in soil, water and sewage. A
	nosocomial infection can cause septicemia, meningitis and urinary tract
	infections.
Aspergillus niger	Black mold, found in shower and dressing rooms. Environmental contaminant
	may also cause "Aspergillosis."
Bordetella bronchiseptica	Gram negative (spherical shape) bacteria. Causative agent for "puppy cough" in
	dogs. Bordetella pertusis is the causative agent for whooping cough in children.
Candida albicans	Fungi, yeast. This organism exhibits dimorphism; exists both as fungi and yeast.
	Causes skin rashes. Common cause for diaper rash. Can infect both oral and
	vaginal cavities. Causes itching and discomfort.
Chlamydia psittaci	Once believed to be a large virus but later found to be a parasitic bacterium.
	Infections cause fever, malaise and hacking cough. Most infections are
	occupational; poultry workers and other keepers of birds.
Enterobacter aerogenes	Gram negative bacteria spread by anal/oral route of infection. Associated with
	bacteremia, respiratory, wound and urinary tract infections.
Enterobacter cloacae	Gram negative bacteria spread by anal/oral route of infection. Associated with
	bacteremia, respiratory, wound and urinary tract infections.
Fusobacterium necrophorum	Gram negative (rod shape) bacteria. Causative agent of "hoof rot" in sheep,
-	cattle and horses.

⁹ Microbiology, D. Kingsbury and G. Wagner Harwal Publishing 1990

Summary of Antimicrobial Efficacy - Etiology - (Continued)

Pathogenic Microorganism	Description
Escherichia coli	Gram negative bacteria spread by anal/oral route of infection, resulting in diarrhea outbreaks. Associated with urinary tract infections and bacteremia.
Legionella pneumophila	Gram negative (rod shape) bacteria. Causative agent for "legionnaire disease." First documented outbreak occurred in 1976 at Philadelphia American Legion convention.
Listeria monocytogenes	Gram positive (rod shape) bacteria. Considered a potent food pathogen. Found in raw meat and poultry. Infections can result in meningitis or sepsis.
Klebsiella pneumoniae	Gram negative bacteria associated with severe pneumonia, bacteremia and urinary tract infections.
Pasteurella multocida	Gram negative (spherical shape) bacteria. Human infections are a result of an animal bite. Indigenous flora of many animals respiratory tracts.
Proteus mirabilis	Gram negative (rod shape) bacteria. Highly motile bacteria. Opportunistic pathogen causes bacteremia, urinary tract infections, especially with the chronically ill.
Proteus vulgaris	Gram negative (rod shape) bacteria. Highly motile bacteria. Opportunistic pathogen causes bacteremia, urinary tract infections, especially with the chronically ill.
Salmonella enteritidis	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea.
Salmonella schottmuelleri	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea.
Salmonella typhi	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea, the causative agent for typhoid fever.
Salmonella typhimurium	Gram negative (rod shape) bacteria associated with acute gastroenteritis and diarrhea.
Serratia marcescens	Gram negative bacteria associated with urinary tract infections, meningitis and septicemia.
Shigella dysenteriae	Gram negative bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects resulting in bacillary dysentery.
Shigella flexneri	Gram negative bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects resulting in bacillary dysentery.

Summary of Antimicrobial Efficacy - Etiology - (Continued)

Pathogenic Microorganism	Description
Shigella sonnei	Gram negative bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects resulting in bacillary dysentery.
Streptococcus (Enterococcus) faecalis	Gram positive (Enterococci) bacteria causing hemolysis, urinary tract infections and endocarditis.
Trichophyton mentagrophytes	Athlete's foot fungus. Found in shower and dressing rooms. Also the causative agent of Ring Worm, a fungi that is transmitted through non-socomal contact (e.g. activity mats, wrestling mats, etc)
Adenovirus Type 4	Lipophilic (enveloped) DNA virus, (one of several) causative agent for colds and other respiratory ailments.
Canine Distemper	Lipophilic (enveloped) RNA virus. Highly contagious among dogs causes fever, gastrointestinal and respiratory symptoms.
Feline Leukemia Virus	Non-enveloped RNA virus. One of the causative agents of lyphosarcoma in cats.
Hepatitis B virus (HBV)	A hepadnavirus, a relatively new class of viruses. Partially double stranded DNA virus with three distinct morphologies. A blood borne pathogen causes serious degeneration of the liver.
Hepatitis C virus (HCV)	A hepadnavirus, a relatively new class of viruses. Partially double stranded DNA virus with three distinct morphologies. Often referred to as Non-A, Non-B Hepatitis. A blood borne pathogen causes degeneration of the liver.
Herpes Simplex Type 1&2	Lipophilic (enveloped) DNA virus may result in oral mucocutaneous lesions. Associated with most orofacial herpes and HSV encephalitis.
HIV-1 (AIDS Virus)	Lipophilic (enveloped) RNA retrovirus. Human Immunodeficiency Virus. Known to be the etiologic agent of Acquired Immunodeficiency Syndrome (AIDS).
Influenza A/Hong Kong	Lipophilic (enveloped) RNA virus. Causative agent in viral flu. Causes flu epidemics in nearly 2 of every 3 years.
Rabies	A member of the Rhabdoviridae family or RNA viruses. These bullet shaped viruses are enveloped by a lipid bilayer. The causative agent for "rabies", an encephalitis that causes neuronal degeneration almost always fatal.
Respiratory Syncytial Virus	A paramyxovirus type virus, lipophilic (enveloped). A causative agent of pneumonia and bronchiolitis in small children and infants. Highly contagious, transmitted by person-to-person contact.
Rubella	Lipophilic (enveloped) RNA togavirus. The causative agent of German measles.
Vaccinia	Lipophilic (enveloped) DNA poxvirus; causes poxvirus infections.