

NEUTRAFECT FORMULATION HWS-64

Description

Formulation **HWS-64** 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. Biocidal performance is attained when this product is properly diluted at 2 oz. per gallon or 1:64. Formulation **HWS-64** can be used to disinfect a wide variety of hard surfaces such as floors, walls, and countertops in hospitals, households, and institutions.

Formula:

	Formulation HWS-64 <u>%wt/wt</u>
<u>Active Ingredient</u>	
FMB [®] 1210-8 (80% active)	5.3
<u>Inert Ingredients</u>^{1,2}	
Ethylenediamine tetraacetic acid	0.2
Tetrasodium ethylenediamine Tetraacetate 38%	1.4
FMB [®] AO-8	5.25
Dye	0.00 to 0.10
Fragrance	0.00 to 1.00
Water	q.s. to 100.00

Regulatory Summary

EPA Registration No.	47371-131
USDA Authorization	A4,C1, D1
California Status	Registered
Canadian PCP#	24879
Canadian Din #	01944045

Physical Properties

pH of Concentrate	7.2-8.2	Flash Point (PMCC)	>200°F
Specific Gravity @ 25°C	0.99	% Quat (mol. wt.360.5)	4.02-4.44
Pounds per gallon @ 25°C	8.34	% Volatile	93.5 - 94.5

¹ See approved list of suppliers

² See Confidential Statement of Formulation for exact ingredients and amounts. If you have any questions please call Lonza Tech Service at 800-365-8324 or contact.allendale@lonza.com

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Summary of Antimicrobial Test Results

Formulation **HWS-64** 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: Disinfectant	Contact Time: 10 minutes	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: Official Method of the AOAC, 14 Edition Use Dilution Method			

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Acinetobacter calcoaceticus	23055	660 ppm (2 oz/gal)	400 ppm	10, 10	0/10, 0/10
Bordetella bronchiseptica	31427	660 ppm	400 ppm	10, 10	0/10, 0/10
Chlamydia psittaci	VR-854	660 ppm	400 ppm	10, 10	0/10, 0/10
Enterobacter aerogenes	13048	660 ppm	400 ppm	10, 10	0/10, 0/10
Enterobacter cloacae	23355	660 ppm	400 ppm	10, 10	0/10, 0/10
Enterococcus (Streptococcus) faecalis (Vancomycin Resistant)	51299	660 ppm	400 ppm	10, 10	0/10, 0/10
Escherichia coli	11229	660 ppm	400 ppm	10, 10	0/10, 0/10
Escherichia coli ¹ (Clinical Isolate)	(Clinical Isolate)	660 ppm	400 ppm	10, 10	0/10, 0/10
Fusobacterium necrophorum	27852	660 ppm	400 ppm	10, 10	0/10, 0/10
Klebsiella pneumoniae ²	13883	660 ppm	400 ppm	10, 10	0/10, 0/10
Legionella pneumophila	33153	660 ppm	400 ppm	10, 10	0/10, 0/10
Listeria monocytogenes	15313	660 ppm	400 ppm	10, 10	0/10, 0/10
Pasteurella multocida	7707	660 ppm	400 ppm	10, 10	0/10, 0/10
Proteus mirabilis	25933	660 ppm	400 ppm	10, 10	0/10, 0/10
Proteus vulgaris	13315	660 ppm	400 ppm	10, 10	0/10, 0/10
Pseudomonas aeruginosa	15442	660 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
Pseudomonas aeruginosa ³	Clinical Isolate	660 ppm	400 ppm	10, 10	0/10, 0/10
Salmonella choleraesuis	10708	660 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
Salmonella enteritidis	13076	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	14028	660 ppm	400 ppm	10, 10	0/10, 0/10
Serratia marcescens	8100	660 ppm	400 ppm	10, 10	0/10, 0/10
Shigella Flexneri	12022	660 ppm	400 ppm	10, 10	0/10, 0/10
Shigella Sonnei	9290	660 ppm	400 ppm	10, 10	0/10, 0/10

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

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

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

Organism	ATCC#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Staphylococcus aureus	6538	660 ppm	400 ppm	60, 60, 60	0/60, 0/60, 0/60
Staphylococcus aureus (MRSA) ⁷	33592	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus aureus ⁴ (VISA)	CDC No. HIP-5836	660 ppm	400 ppm	10, 10	0/10, 0/10
Staphylococcus epidermidis ⁵	Clinical Isolate	660 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus (Enterococcus) faecalis	19433	660 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus (Enterococcus) faecalis ⁶	19433	660 ppm	400 ppm	10, 10	0/10, 0/10
Streptococcus pyogenes	19615	660 ppm	400 ppm	10, 10	0/10, 0/10

Conclusion: All lots of Formulation **HWS-64** effectively killed the above listed bacteria as specified in the test performance standards. Formulation **HWS-64** meets EPA requirements for hard surface disinfectant claims in hospital and medical environments when diluted as directed.

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#	Use-Dilution Concentration	Hard Water Condition	Replicates	Results
Aspergillus niger	6275	660 ppm (2.0 oz/gal)	400 ppm	10, 10	0/10, 0/10

Conclusion: All lots of Formulation **HWS-64** were effective against Aspergillus niger under the test conditions outlined in the EPA test performance standards described above.

Claim: Fungicide	Contact Time: 10 minutes	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: Official Method of Analysis of the AOAC Fungicidal Test.			

Organism	ATCC#	Dilution	Replicates	Results		
				5 Min	10 Min	15 Min
Candida albicans	11651	660 ppm (2 oz/gal)	4	0/4 +	0	0
Trichophyton mentagrophytes	9533	660 ppm (2 oz/gal)	4	0/4 +	0	0

4 Reduced Susceptibility to Vancomycin

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

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

7 Resistant to Methicillin

Conclusion: All lots of Formulation **HWS-64** effectively killed Trichophyton mentagrophytes and Candida albicans as specified in the test performance standards.

Claim: Virucide	Contact Time: Varies	Organic Soil: 5%	Water Conditions: 400 ppm as CaCO ₃
Test Method: EPA Guidelines			

Organism	Source of Virus or ATCC#	Host System; Cytopathic Effect	Use-Dilution Concentration	Contact Time	Reduction (Log 10) of Virus Titer
Adenovirus Type 4	ATCC VR-4 strain RI-67	H. Ep. #2 cells Cytopathic Effects	660 ppm (2.0 oz/gal)	10 Min.	5.5, 5.5
Adenovirus Type 7	ATCC VR-7	HeLa cells ATCC CEL-1958	2644 ppm (8 oz/gal)	10 Min.	>3.5, >3.5
Hepatitis B Virus (HBV)	Hepadna Virus, Inc. (DHBV)	Primary Duck Hepaocytes; No Cytopathic Effects	660 ppm	10 Min.	4.8, 4.8
Hepatitis C Virus (HCV)	Bovine Viral Diarrhea Virus	MDBK Cells	660 ppm	10 Min.	5.5, 5.7
Herpes Simplex Type 1	HSV-1; ATCC VR-733	VERO cells; lytic cytopathic effect	660 ppm	10 Min.	>7.5, 7.5
Herpes Simplex Type 2	HSV-2; MS Strain	VERO cells; lytic cytopathic effect	660 ppm	10 Min.	>6.5, 6.5
HIV-1 (AIDS Virus)	HTLV-III _{RF} ; NCI	MT2 cells; lytic cytopathic effect	660 ppm	4 Min.	>3.0, 3.0
Human Corona Virus	VR-740 Strain 229E	MRC-5 Host	660 ppm	10 Min	>4.0, >4.0
Influenza A/ Hong Kong	ATCC 68-H3N2	MDCK cells; lytic cytopathic effect	660 ppm	10 Min.	>8.0, 8.0
Rubella virus	Strain M-33	RK13 cells; cytopathic effect	660 ppm	10 Min.	>5.0, 5.0
Rabies virus	ATCC VR-138		660 ppm	10 Min.	4.5, 4.5
Respiratory Syncytial virus	ATCC VR-26		660 ppm	10 Min.	4.0, 4.5
SARS associated Coronavirus	Vero E6 coronavirus	Vero E6 Cells	660 ppm	10 Min	3.5, 3.5, 3.5
Vaccinia	Strian IHD	VERO Cells; lytic cytopathic effect	660 ppm	10 Min.	>7.0, 7.0
Avian Infectious Bronchitis virus	ATCC VR-22		660 ppm	10 Min.	6.0, 6.25
Avian Polyomavirus	lab isolate		660 ppm	10 Min	4.0, 6.0
Canine Distemper virus	ATCC-VR-256		660 ppm	10 Min.	3.5, 3.5
Feline Leukemia Virus	ATCC VR-717 Strain FL-237		660 ppm	10 Min.	4.5, 4.75
Feline Picornavirus	ATCC VR-649		660 ppm	10 Min.	5.0, 5.0

Infectious Bovine Rhinotracheitis	ATCC VR-793		660 ppm	10 Min.	8.0,8.0
Newcastle Disease Virus	ATCCC VR-108 Strain B1 Hitchner or Blacksburg	Chicken embryo fibroblast cells	660 ppm	10 Min.	≥4.0, ≥4.0
Pseudorabies Virus	ATCC VR-135		660 ppm	10 Min.	5.5, 5.5
Transmissible Gastroenteritis	ATCC VR-763		660 ppm	10 Min.	3.5, 3.5

Conclusion: All lots of Formulation **HWS-64** effectively inactivated the above listed viruses as specified in the test performance standards. Formulation **HWS-64** meets EPA requirements for hard surface virucidal claims in hospital and medical environments.

Summary of Antimicrobial Efficacy – Etiology⁸

Pathogenic Microorganism	Description
Acinetobacter calcoaceticus	Gram negative (spherical shape) bacteria. Occurs in soil, water and sewage. A nosocomial infection can cause septicemia, meningitis and urinary tract infections.
Adenovirus Type 4	Lipophilic (enveloped) DNA virus, (one of several) causative agent for colds and other respiratory ailments.
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 pertussis 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.
Canine Distemper	Lipophilic (enveloped) RNA virus. Highly contagious among dogs causes fever, gastrointestinal and respiratory symptoms.
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.
Escherichia coli	Gram negative bacteria spread by anal/oral route of infection, resulting in diarrhea outbreaks. Associated with urinary tract infections and bacteremia.
Feline Leukemia Virus	Enveloped RNA virus. One of the causative agents of lymphosarcoma in cats.
Fusobacterium necrophorum	Gram negative (rod shape) bacteria. Causative agent of “hoof rot” in sheep, cattle and horses.
HBV (Hepatitis B virus)	Lipophilic (enveloped) DNA virus of the Hepadnaviridae family. Causative agent of Hepatitis B (serum hepatitis).
HCV (Hepatitis C Virus)	Major cause of acute hepatitis and chronic liver disease, including cirrhosis and liver cancer. It is an enveloped RNA virus in the flaviviridae family.

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).
Human Corona Virus	Single Strand RNA containing virus causing respiratory infection in humans. From order Nidovirales and Family Coronaviridae.
Influenza A/Hong Kong	Lipophilic (enveloped) RNA virus. Causative agent in viral flu. Causes flu epidemics in nearly 2 of every 3 years.
Klebsiella pneumoniae	Gram negative bacteria associated with severe pneumonia, bacteremia and urinary tract infections.
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.
Newcastle Disease Virus	NDV is a contagious and fatal viral disease affecting most species of birds. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. NDV can infect and cause death even in vaccinated poultry.

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.
Pseudomonas aeruginosa	Gram negative bacteria identified as a major cause of hospital acquired (nosocomial) infections. Causes wound infections (especially burn), meningitis, pneumonia and eye infections. Required for Hospital Disinfectants.
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.
Salmonella choleraesuis	Gram negative bacteria associated with acute gastroenteritis and septicemia. Required for Hospital Disinfectants.
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.
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.
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, osteomyelitis and pneumonia. Required for Hospital Disinfectants.
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.
Vaccinia	Lipophilic (enveloped) DNA poxvirus; causes poxvirus infections.

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

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Supercedes: 5-5-07