Clean Room Efficacy Data / Kill Data

Clean Room® Disinfectant/Sanitizer

Description

Clean Room® (3.85%, 14.08%, 50%) are broad spectrum, hard surface disinfectant/sanitizers. When used as directed, these products will deliver effective biocidal action against bacteria, fungi, and viruses. These formulations are blends of active ingredient, FMB 1210-8 or FMB-1210-5, and water. Biocidal performance is attained when these products are properly diluted with water. **Clean Room® (3.85%, 14.08%, 50%)** can be used to sanitize food contact surfaces such as countertops, glasses and utensils as well as to disinfect a wide range of hard surfaces such as floors, walls and countertops. Other use areas include hospitals, nursing homes, medical clinics, dental offices, schools, colleges, office buildings, hotels and motels, breweries, federally inspected meat and poultry plants, veterinary clinics, poultry and hog farms, dairy farms, and kennels.

Formulation Details (3.85%):

	Clean Room® Disinfectant/Sanitizer (3.85%)	**Clean Room® Disinfectant/Sanitizer (3.85%)**
	%wt/wt	**%wt/wt**
Active Ingredient		
FMB® 1210-8 (80% active)	4.82	------
May be formulated with FMB® 1210-5 if no dyes are used		
FMB® 1210-5 (50% active)	-----	7.7
Inert Ingredients		
Dye[1]	0.00 to 0.50	0.00 to 0.50
Water	q.s. to 100.0	q.s. to 100.00

Regulatory Summary

EPA Registrated	
Prior USDA Authorization	**D2**
California Status	**Registered**

Physical Properties

pH of Concentrate	6.0-8.0
Specific Gravity @ 25°C	1.00
Pounds per gallon @ 25°C	8.34

Flash Point (PMCC)	>200°F
% Quat	3.85

Formulation Details (14.08%):

	Formulation Disinfectant/Sanitizer (14.08%) %wt/wt	Formulation Disinfectant/Sanitizer (14.08%) %wt/wt
Active Ingredient		
FMB® 1210-8 (80% active)	17.60	------
May be formulated with FMB® 1210-5 if no dyes are used		
FMB® 1210-5 (50% active)	-----	28.16
Inert Ingredients		
Dye[1]	0.00 to 0.50	0.00 to 0.50
Water	q.s. to 100.0	q.s. to 100.00

Regulatory Summary

EPA Registered	
USDA Authorization	**D2**
California Status	**Registered**

Physical Properties

pH of Concentrate	6.0-8.0
Specific Gravity @ 25°C	1.00
Pounds per gallon @ 25°C	8.34

Flash Point (PMCC)	>200°F
% Quat (mol. wt. 342)	14.08

Formulation Details HS1210 (50%):

	Formulation (50%) %wt/wt	Formulation (50%) %wt/wt
Active Ingredient		
FMB® (80% active)	62.5	
May be formulated with FMB® 1210-5 if no dyes are used		
FMB® 1210-5 (50% active)		100
Inert Ingredients		
Dye[1]	0.0 to 0.50	
Water	q.s. to 100.00	

Regulatory Summary

EPA Registered	
Prior USDA Authorization	**D2**
California Status	**Registered**

Physical Properties

pH of Concentrate	6.0-8.0
Specific Gravity @ 25°C	0.95
Pounds per gallon @ 25°C	7.88

Flash Point (PMCC)	114° F
% Quat (mol. wt. 342)	50.0

Summary of Antimicrobial Test Results

Clean Room® (3.85%, 14.08%, 50%) are "One-Step" Hospital Disinfectants, Fungicides, Sanitizers and Viricides. Listed below, and in the following pages, are a summary of the Antimicrobial Claims and a review of the test results.

Claim: Disinfectant	**Contact Time:** 10 minutes	**Organic Soil:** 5%	**Water Conditions:** Deionized
Test Method:	Official Method of the AOAC, 15 Edition - Use-Dilution Method		
Organism	**ATCC#**		**Use-Dilution Concentration**
Campylobacter jejuni	29428		550 ppm
Enterobacter aerogenes	13048		500 ppm
Escherichia coli	11229		500 ppm
Klebsiella pneumoniae	13883		500 ppm
Listeria monocytogenes	19115		550 ppm
Mycoplasma gallisepticum	19610		500 ppm
Proteus mirabilis	Clinical Isolate		500 ppm
Pseudomonas aeruginosa	15442		500 ppm
Salmonella Enterica	10708		500 ppm
Salmonella typhi	6539		500 ppm
Serratia marcescens	8100		500 ppm
Shigella flexneri	9199		500 ppm
Staphylococcus aureus	6538		500 ppm
Staphylococcus aureus Phage 80	Clinical Isolate		500 ppm
Staphylococcus aureus Phage 81	Clinical Isolate		500 ppm
Streptococcus pyogenes	19615		500 ppm
Vibrio anguillarum	19264		550 ppm

Conclusion: All lots of **Clean Room® (3.85%, 14.08%, 50%)** effectively killed the above listed bacteria as specified in the test performance standards. **Clean Room® (3.85%, 14.08%, 50%)** meet EPA requirements for hard surface disinfectant claims in hospital and medical environments when diluted to 500 ppm or 550ppm active ingredient in the presence of 5% organic soil.

Claim:	Contact Time:	Organic Soil:	Water Conditions:
Virucide	10 minutes	5%	Deionized
Test Method:	EPA Guidelines		

Organism	Source of Virus or ATCC#	Use-Dilution Concentration
Avian Infectious Bronchitis virus	ATCC VR-22	500 ppm
Avian Influenza Virus (H5N1)	Strain VNH5N1-PR8/CDC-RG CDC# 2006719965	550 ppm
Infectious Bovine Rhinotracheitis	ATCC VR-793	500 ppm
Infectious Bronchitis Virus – Arkansas Strain	Primary Chicken Embroyo Fibroblasts	500 ppm
Marek Disease Virus	Embryonated chick eggs	500 ppm
Newcastle Disease	ATCC-VR-109	500 ppm

Conclusion: All lots of **Clean Room® (3.85%, 14.08%, 50%)** effectively inactivated the above listed viruses as specified in the test performance standards. **Clean Room® (3.85%, 14.08%, 50%)** meets EPA requirements for hard surface virucidal claims in hospital and medical environments when diluted to 500 ppm or 550ppm active ingredient in the presence of 5% organic soil**.**

Claim:	Contact Time:	Organic Soil:	Water Conditions:
Sanitizer, Food Contact Surfaces	60 seconds	Pre-clean	500 ppm $CaCO_3$
Test Method:	Sanitizer: AOAC Germicidal and Detergent Sanitizer, For Inanimate, Food Contact Surfaces		

Organism	ATCC#	Use-Dilution Concentration
Escherichia coli	11229	150 ppm
Staphylococcus aureus	6538	150 ppm

Conclusion: All lots of **Clean Room® (3.85%, 14.08%, 50%)** effectively killed the above listed bacteria as specified in the test performance standards with greater than 99.999% reduction within one minute. **Clean Room® (3.85%, 14.08%, 50%)** are effective Food Contact Sanitizers against the above listed bacteria on hard non-porous surfaces when diluted to 150 ppm active ingredient in 500 ppm $CaCO_3$ synthetic hard water.

Claim:	Contact Time:	Organic Soil:	Water Conditions:
Sanitizer, Food Contact Surfaces	60 seconds	Pre-clean	500 ppm $CaCO_3$
Test Method:	Sanitizer: AOAC Germicidal and Detergent Sanitizer, For Inanimate, Food Contact Surfaces		

Organism	ATCC#	Use-Dilution Concentration
Campylobacter jejuni	29428	200 ppm (1 oz/19.5 gal)
Escherichia coli	11229	200 ppm
Escherichia coli 0157:H7	35150	200 ppm
Listeria monocytogenes	19115	200 ppm
Shigella sonnei	11060	200 ppm
Salmonella choleraesuis	10708	200 ppm
Staphylococcus aureus	6538	200 ppm
Vibrio cholerae	14035	200ppm
Yersinia enterocolitica	9610	200 ppm

Conclusion: All lots of **Clean Room® (3.85%, 14.08%, 50%)** effectively killed the above listed bacteria as specified in the test performance standards with greater than 99.999% reduction within one minute. **Clean Room® (3.85%, 14.08%, 50%)** are effective Food Contact Sanitizers against the above listed bacteria on hard non-porous surfaces when diluted to 200 ppm active ingredient in 500 ppm $CaCO_3$ synthetic hard water.

Claim:	Contact Time:	Organic Soil:	Water Conditions:
Bacterial Black Spot Tomatoes Control		Pre-clean	Deionized
Test Method: Efficacy Testing of Formulations for the Control of Citrus Canker: USDA guidelines			Test (Host) Plant: Yolo Wonder Pepper Plant

Organism	Use-Dilution Concentration
Xanthomonas campestris pv. vesicatoria	2000 ppm (5 oz/9.75 gal)

Conclusion: All lots of **Clean Room® (3.85%, 14.08%, 50%)** effectively killed the above listed bacteria as specified in the test performance standards. **Clean Room® (3.85%, 14.08%, 50%)** meets EPA requirements for Black Spot Tomatoes Control claims when diluted to 2000 ppm active ingredient and label directions are followed.

Claim:	Contact Time:	Organic Soil:	Water Conditions:
Fungicide	10 minutes	5%	Deionized
Test Method:	Official Method of Analysis of the AOAC - Fungicidal Test.		

Organism	ATCC#	Use-Dilution Concentration
Alternaria tenius	6663	550 ppm (2 oz/ 14 gal)
Aspergillus glaucus	16440	500 ppm (2 oz/15.5 gal)
Candida albicans	10231	500 ppm
Fusarium oxysporum	48112	550 ppm
Geotrichum candidum	34614	550 ppm
Penicillium digitatum	48113	550 ppm
Phytophthora infestans	60651	550 ppm
Rhizopus nigricans [stolonifer]	14037	550 ppm
Trichoderma harzianum	48134	550 ppm
Trichophyton mentagrophytes	9533	500 ppm

Conclusion: All lots of **Clean Room® (3.85%, 14.08%, 50%)** effectively killed fungi as specified in the test performance standards. **Clean Room® (3.85%, 14.08%, 50%)** is an effective fungicide for nonporous inanimate hard surfaces when diluted to 500 ppm or 550ppm active ingredient in the presence of 5% organic soil.

Summary of Antimicrobial Efficacy - Etiology

Pathogenic Microorganism	Description
Alternaria tenius	mold - common allergen found in soil and household areas, esp water damaged areas. Can be found on carpets and textiles and window frames.
Aspergillus glaucus	Mold, (mildew) found in shower and dressing rooms. Environmental contaminant may also cause “Aspergillosis.”
Avian Infectious Bronchitis Virus	Is a coronavirus that infects chickens, causing associated disease, and infectious bronchitis.
Avian Influenza H5N1	H5N1 is a type of influenza virus that causes a highly infectious, severe respiratory disease in birds called avian influenza (or "bird flu"). Human cases of H5N1 avian influenza occur occasionally, but it is difficult to transmit the infection from person to person.
Campylobacter jejuni	Gram negative bacteria associated with acute gastroenteritis. Spread by anal/oral route of infection, resulting in diarrhea outbreaks.
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.
Citrus Canker Virus	A highly contagious disease for citrus crops caused by bacteria which can defoliate crops as well as reduce fruit quality and cause premature fruit drop.
Enterobacter aerogenes	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.
Fusarium oxysporum	Asexual fungus that can produce three types of spores, microconidia, macroconidia and chlamydospores.
Geotrichum candidum	An extremely common fungus with a world-wide distribution and is the causative agent of geotrichosis. Pulmonary involvement is the most frequently reported form of the disease, but bronchial, oral, vaginal, cutaneous and alimentary infections have also been reported
Infectious Bovine Rhinotracheitis	An acute contagious respiratory disease of cattle caused by bovine herpes virus type 1 (BHV-1) affecting respiratory tract and reproductive system.
Infectious Bronchitis Virus – Arkansas Strain (IBV)	Effects are loss of egg production in chickens.
Klebsiella pneumoniae	Gram negative bacteria associated with severe pneumonia, bacteremia and urinary tract infections.
Listeria monocytogenes	Listeria monocytogenes is a Gram-positive rod-shaped bacterium. It is the agent of listeriosis, a serious infection caused by eating food contaminated with the bacteria
Marek’s Disease Virus	A chicken herpes virus causing abnormal cell growth on peripheral nerves and central nervous system of fowl, causing paralysis. Spread by dander on feather follicles, it can be excreted in saliva and can enter respiratory system.
Mycoplasma gallisepticum	Most pathogenic avian mycoplasma, resulting in swollen infraorbital sinues in chickens and turkeys
Newcastle Disease	A viral infection in poultry transmitted by inhalation of infectious aerosols which can affect humans.
Penicillium digitatum	Devastating pathogen of citrus fruit.

Phytophthora infestans	Pathogen of food crops causing potato blight. Produces microscopic asexual spores called sporangia.
Proteus mirabilis	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.
Rhizopus Nigricans (stolonifer)	Fungi of genus Rhizopus causing bread mold.
Salmonella choleraesuis	Gram negative bacteria associated with acute gastroenteritis and septicemia. Required for Hospital Disinfectants.
Trichoderma harzianum	Filamentous fungus used as a fungicide.

Salmonella typhi	Gram negative (rod shaped) bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects Causative agent for typhoid fever.
Serratia marcescens	Gram negative bacteria associated with urinary tract infections, meningitis and septicemia.
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 sonneii	Gram positive bacteria that causes gastroenteritis.
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.
Streptococcus (Enterococcus) pyogenes	Gram positive (Enterococci) bacteria causing hemolysis, urinary tract infections and endocarditis. Causative agent of pharyngotonsillitis (sore throats).
Trichophyton mentagrophytes	Athlete's foot fungus. Found in shower and dressing rooms.
Vibrio anguillarum	Gram negative, rod bacterium pathogen in fish.
Vibrio cholerae	Gram negative, rod shape bacteria; causative agent for cholerae – causes severe diarrhea -- often fatal.
Yersinia enterocolitica	Infectious disease caused by a bacterium of the genus Yersinia. Belongs to a family of rod-shaped bacteria. Infection is most often acquired by eating contaminated food, especially raw or undercooked pork products.