MONOFOIL-D VIRUCIDAL , DISINFECTANT

COMMERCIAL LINE TECHNICAL REPORT

MonoFoil-D: COMMERCIAL LINE TECHNICAL REPORT

PRODUCT DESCRIPTION:

MonoFoil-D is a colorless, odorless, ready-to-use Healthcare grade disinfectant multi-surface spray. The MonoFoil-D dual Action active system creates a barricade against microbes on your surfaces. MonoFoil-D contains no harsh acids, phosphates. Has no harsh chemical odor and leaves no residue. MonoFoil-D aids in the reduction of cross contamination of germs and antibiotic resistant bacteria on soft and hard, non-porous surfaces. Protect your surfaces with an Antimicrobial Shield that lasts between cleanings.

INGREDIENTS:

ACTIVE INGREDIENTS:

3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride…….....0.13%
N-Alkyl Dimethyl Benzyl Ammonium Chloride (60% C14, 30% C16, 5% C18, 5% C12)…….0.25%
N-Alkyl Dimethyl Ethylbenzyl Ammonium Chloride (68% C12, 32% C14)…….....0.25%
INERT INGREDIENTS:…….....99.37%
TOTAL:…….....100%

REGISTRATION:

MONOFOIL D is registered with the U.S. Environmental Protection Agency. EPA

REG. NO.: 90856-4

EPA EST. NO.: 087250-IN-001
087250-IN-002

Patents pending

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DIRECTION FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DISINFECTION:

Areas of Application:
Homes, offices, hospitals, restaurants, schools, hotels, restrooms, recreational facilities, public transport vehicles.

Use on painted, glazed tile, plastic, metal, glass and glazed porcelain, textiles

To disinfect hard and soft surfaces: Pre-clean surfaces prior to disinfecting.
Apply MonoFoil D directly to the surface until thoroughly wet for the contact time as listed. Wipe dry with a clean towel.

Residual Protection: When used as directed, this product provides residual protection up to 24 hours after initial application.

BACTERIA:

ORGANISM	CONTACT TIME*
Pseudomonas aeruginosa	30 seconds
Salmonella enterica	30 seconds
Staphylococcus aureus	2 minutes
Listeria monocytogenes	2 minutes
Vancomycin resistant *Enterococcus faecium* (VRE)	2 minutes
Methicillin resistant *Staphylococcus aureus* (MRSA)	2 minutes
Community Associated MRSA (CA-MRSA)	2 minutes
Community Associated MRSA (CA-MRSA-PVL)	2 minutes
Escherichia coli O157:H7	2 minutes
Acinetobacter baumannii	2 minutes
Campylobacter jejuni	2 minutes
Carbapenem resistant *Escherichia coli*	2 minutes
Carbapenem resistant *Klebsiella pneumoniae*	2 minutes
Carbapenem resistant *Klebsiella pneumonia, NDM-1*	2 minutes

VIRUSES:

ORGANISM	CONTACT TIME*
HIV type 1	30 seconds
Rotavirus	30 seconds
Human Coronavirus	30 seconds
Avian Influenza A	30 seconds
Influenza A	30 seconds
Influenza A (H1N1)	30 seconds
Swine Influenza A (H1N1)	30 seconds
Respiratory Syncytial Virus	30 seconds
Adenovirus Type 2	30 seconds
Herpes Simplex Type 1	60 seconds
Murine Norovirus	60 seconds
Norovirus	60 seconds
Rhinovirus	60 seconds
Polio Type 2	60 seconds
Hepatitis B Virus (HBV)	60 seconds
Hepatitis C Virus (HCV)	60 seconds

FUNGUS:

ORGANISM	CONTACT TIME*
Trichophyton mentagrophytes (Athlete's Foot Fungus)	5 minutes

DISINFECTION OF HARD AND SOFT SURFACES

AREAS OF APPLICATION:
Hospitals, homes, schools, hotels, dental offices, commercial buildings. Use on surfaces such as fixtures, glass, furniture, Porcelain, stainless steel, plastic, textiles.

HARD SURFACE: Spray Shake well. Shake well. MONOFOIL D comes ready to use. Spray directly onto surface, spray entire surface area 4”-6” from hard, non-porous surface until completely wet; surface must remain wet for 10 minutes and then allow to air dry.

SOFT SURFACE: Spray Shake well. Shake well. MONOFIL D comes ready to use. Spray directly onto surface, spray entire surface area 4”-6” from hard, porous surface until completely wet; surface must remain wet for 3 minutes and then allow to air dry.

POULTRY ANIMAL APPLICATIONS:

To disinfect animal processing equipment and other surfaces.

Veterinary Practice/Kennels/Poultry houses/Animal Care Facilities: For disinfecting hard, non-porous surfaces including equipment, utensils, cages, kennels, hatchers, setters, trays, racks, egg flats, walls, floors, ceilings, chick boxes, egg cases, vans, trash containers and teat and milking equipment etc. Remove all animals and feeds from the premises, crates, cages, and enclosures. Remove all litter, droppings, and manure from floors walls, and surfaces occupied or traversed by animals. Empty all troughs, racks and other feeding/watering appliances. Thoroughly clean surfaces with (This product). Do not house animals or employ equipment until treatment has been absorbed, set, and dried.

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MECHANISM OF ACTION

The MonoFoil active ingredient (A.I.) in aqueous solution is known to have high antimicrobial activity. In water, the A.I., 3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride will hydrolyze into a silane triol. The ability of this molecule to kill virus, bacteria in solution is high (MIC *Avian Influenza ≥ 5.5 log10*). As this molecule reacts with receptive surfaces, the ability for it to orient into subsequent monolayers leads to the formation of a covalently bound, very potent durable antimicrobial.

The mode of action of the MonoFoil surface bound polymer is directed specifically at the inner membrane of the cell. This cellular membrane is fluid. The phosphorlipids that make up the backbone of the membrane are in constant motion.

It is this fluidity that allows for the trans- port of food and energy throughout the cell and is responsible for the entire integrity of the organism itself. If this membrane fluidity is disrupted, the cell will die.

As the hydrolyzed A.I. reacts with the surface, it transforms from a silane triol monomer (found in solution) to a covalently linked polymer matrix. It is only in this polymer matrix that full durable antimicrobial activity is obtained. As the bacteria, virus or fungi contact the polymer matrix, the MonoFoil polymer integrates into the membrane. A one micron cell organism contacts a treated surface and is exposed to approximately 25,000 molecules of the A.I. concentrated at a single site. It is this concentrated attack that disrupts the fluidity of the membrane and ruptures the cell. In solution, this concentrated attack on the membrane by the A.I. cannot happen due to the lack of matrix formation and overall concentration of the active ingredient.

MICROBIOLOGICAL TEST DATA

BACTERIAL TEST METHODS:
For registration with the US Environmental Protection Agency (US EPA), disinfection efficacy is tested following either the AOAC Use Dilution Test Method or the AOAC Germicidal Spray Products Test Method. In each method, cultures of bacteria are dried onto a number of small carriers (stainless steel penicylinders in the Use-Dilution test or glass slides in the AOAC Germicidal Spray Products Test). Once dried, the carriers must contain a bacteria concentration of at least 10^4. These carriers are exposed to the disinfectant for a specified contact time and then transferred to test tubes containing growth medium and a neutralizing agent to stop the action of the disinfectant. The carriers are incubated for 48 hours. The tubes are then examined for growth or no growth. To pass a 60 carrier test, three batches are tested and 59 out of 60 carriers must show no growth for each product batch. To pass a 10 carrier test, two batches are tested and all 10 carriers must show no growth.

To make general broad spectrum claims a disinfectant must show efficacy against a *Staphylococcus aureus* (Gram positive bacteria) and *Salmonella enterica* (Gram negative bacteria). To make claim for use in and hospital/medical environments a disinfectant must show efficacy against *Pseudomonas aeruginosa* (nosocomial bacteria). Other bacteria may be tested to obtain additional claims.

ORGANISM	# OF CARRIERS EXPOSED	# OF CARRIERS SHOWING GROWTH	CONTACT TIME	CARRIER POPULATION
Pseudomonas aeruginosa (ATCC#15442)	180	0	30 seconds	10^7
Staphylococcus aureus (ATCC#6538)	180	0	2 minutes	10^7
Salmonella enterica (ATCC#10708)	180	0	30 seconds	10^8
Listeria monocytogenes (ATCC#19111)	20	0	2 minutes	10^6
Vancomycin resistant *Enterococcus faecium* (VRE) (ATCC#700221)	20	0	2 minutes	10^8
Methicillin resistant *Staphylococcus aureus* (MRSA) (ATCC#700698)	20	0	2 minutes	10^8
Community Associated MRSA (CA-MRSA) (NRS123, USA 400)	20	0	2 minutes	10^7
Community Associated MRSA (CA-MRSA-PVL) (NRS 192)	20	0	2 minutes	10^7
Escherichia coli O157:H7 (ATCC#43888)	20	0	2 minutes	10^8
Acinetobacter baumannii (ATCC#19606)	20	0	2 minutes	10^8
Campylobacter jejuni (ATCC#29428)	20	0	2 minutes	10^8
Carbapenem resistant *Escherichia coli*	20	0	2 minutes	10^8
Carbapenem resistant *Klebsiella pneumoniae*	20	0	2 minutes	10^8
Carbapenem resistant *Klebsiella pneumonia*, NDM-1	20	0	2 minutes	10^8

MICROBIOLOGICAL TEST DATA (CONT.)

VIRUCIDAL TEST METHODS:
The US EPA accepts carrier based Virucidal test methods to support Virucidal activity of a disinfectant, which are modifications of the AOAC Use Dilution Test or the AOAC Germicidal Spray Products Test. Each virus claimed must be tested in an appropriate test system using a cell line which supports the growth of the virus.

The method as outlined in the EPA Disinfectant Technical Science section (DIS-TSS 07) states:

To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus is then assayed by an appropriate virological technique.

In order for the data to be considered valid, the following criteria must be met:

1: Virus concentration after drying must be at least 10^4.

2: Complete inactivation of the viruses at all dilutions is required. If cytotoxicity is evident, at least a 3 log reduction of virus concentration must be demonstrated beyond the cytopathic effect.

3: Cell controls must be negative for infectivity.

ORGANISM	DRIED VIRUS CONTROL	LOG REDUCTION	CONTACT TIME
HIV type 1- Strain HTLV IIIB	10^{10}	≥3.5	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain (ATCC VR-733)	10^{10}	≥4.0	60
seconds Rotavirus (Strain WA, Ottawa)		10^{10}	≥4.0
60 seconds			
Human Coronavirus (ATCC VR-740)	10^{10}	≥4.25	30
seconds			
Influenza A (H1N1) (ATCC VR-1469)	10^{10}	≥7.5	30 seconds
Swine Influenza A (H1N1) (ATCC VR-333)	10^{10}	≥6.25	30 seconds
Adenovirus Type 2 (ATCC VR-846)	10^{10}	≥3.0	30 seconds
Norovirus -as Feline Calicivirus (ATCC VR-782)	10^{10}	≥5.88	60 seconds
Avian Influenza A (ATCC VR-2072)	10^{10}	≥5.5	30 seconds
Influenza A (ATCC VR-544)	10^{10}	≥7.5	30 seconds
Rhinovirus (ATCC VR-1147)	$10^{4.5}$	≥4.0	60 seconds
Hepatitis B Virus (HBV)	10^{10}	≥4.7	60
seconds			
Hepatitis C Virus (HCV)	10^{10}	≥5.9	60
seconds			

FUNGAL TEST METHODS:
For registration with the US EPA, efficacy against pathogenic fungi is determined by following the AOAC Fungicidal Test Method or modifications of either the AOAC Use Dilution Test Method modified or the AOAC Germicidal Spray Products Test Method which meet the criteria of the AOAC Fungicidal Test Method. The carrier method is outlined below.

The disinfectant is placed in a water bath and allowed to equilibrate to a temperature of 20.0 °C ± 0.5°C. Carriers will be inoculated with test culture. Carriers must have a minimum concentration of 10^4 after drying. Each contaminated and dried carrier is placed into a test tube containing test substance for the specified contact time and then transferred to test tubes containing growth medium and a neutralizing agent to stop the action of the disinfectant. The carriers are incubated for an appropriate time based upon the test organism. The tubes are examined for growth or no growth. To pass a 60 carrier test, two batches are tested and 59 out of 60 carriers must show no growth for each product batch. To pass a 10 carrier test, two batches are tested and all 10 carriers must show no growth.

ORGANISM	# OF CARRIERS EXPOSED	# OF CARRIERS SHOWING GROWTH	CONTACT TIME
Trichophyton mentagrophytes (Athlete's Foot Fungus) ATCC#9533	10	0	5 minutes

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PHYSICAL DATA:

Appearance	Clear, colorless liquid
Odor	odorless
pH	6.0 – 8.0
Specific Gravity (H2O=1)	1
Solubility	Water soluble
VOC Content (% Wt.)	0.00% (0.000 lbs/gallon)
Flash Point	N/A

STORAGE AND DISPOSAL:

Store in original container in areas inaccessible to small children. Do not reuse empty container. (Replace cap and) discard in trash or offer for recycling if available.

QUESTIONS?

For Customer Service please call: (765) 203-2304

Customer Service Hours of Operation Mon-Fri 9am-4pm EST

Manufactured by MonoFoil USA, LLC

MonoFoil™

Clean Redefined[6]

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