

71654-7

12-16-2009

1/11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 16 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thomas C. McEntee
Product Registration Manager
E.I. du Pont de Nemours and Company
Dupont Chemical Solutions Enterprise, P.O. Box 80402
Wilmington, DE 19880-0402

Subject: **Virkon®**
EPA Registration Number: 71654-7
Application Date: September 28, 2009
Receipt Date: October 1, 2009

Dear Mr. McEntee:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

Revised label to add claim against Swine Influenza A (H1N1) virus

General Comment

A copy of accepted labeling is enclosed for your records.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email at carlisle.sharon@epa.gov, or Lisa McKelvin by telephone at (703) 308-7496 or email at mckelvin.Lisa@epa.gov

Sincerely,

A handwritten signature in cursive script that reads "ShaRon Carlisle".

ShaRon Carlisle
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosed: Stamped Label

[Virkon logo]
Virkon®
Broad Spectrum Disinfectant
[Hospital Disinfectant]

[FOR USE IN: Cleaning and disinfecting hard non-porous surfaces in institutional, commercial, residential and public service facilities including hospitals and nursing homes; field medical units, medical and dental offices; clinics and other health-care facilities; Emergency Medical Services (EMS) facilities, equipment and gear including respirators; laboratories; food processing plants, equipment and warehouses; food service and preparation areas including commercial and institutional kitchens, restaurants and cafeterias; restrooms and portable restrooms; retail stores including supermarkets, florists, barbers, and beauty salons; factories; schools and daycare centers; hotels; offices; correctional facilities; funeral parlors and mortuaries; gymnasiums, stadiums and health spas; transportation terminals and vehicles including ships, automobiles, trucks, trains, and homes and residences.]

[EFFECTIVE AGAINST A WIDE RANGE OF VIRUSES*, BACTERIA AND FUNGI:

* Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV (Human Immunodeficiency Virus (HIV-1) (AIDS virus), Influenza A Virus, Respiratory Syncytial Virus (RSV), Norovirus (Norwalk-like Viruses), Avian Influenza Virus, Swine Influenza A (H1N1) Virus [OPT], Influenza A (H1N1) Virus [OPT], Influenza A H1N1 Virus [OPT].

Bacillus cereus, Campylobacter jejuni, Chlamydia psittaci, Clostridium perfringens, Listeria monocytogenes, Shigella sonnei, Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli O157:H7, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Methicillin-Resistant Staphylococcus aureus (MRSA), Vancomycin-Resistant Enterococcus faecalis, (VRE), Candida albicans, and Trichophyton mentagrophytes]

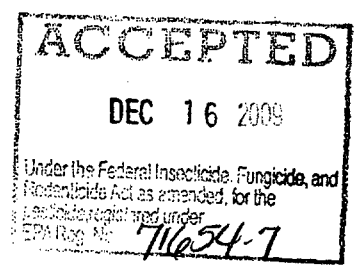
ACTIVE INGREDIENTS	
Potassium peroxymonosulfate	21.41%
Sodium chloride	1.50%
INERT INGREDIENTS	<u>77.09%</u>
TOTAL	100.00%

[Equivalent to 9.75% Available Chlorine]

KEEP OUT OF REACH OF CHILDREN
DANGER / PELIGRO
 See [Back Panel][Box] for Additional Precautions
 [See product insert for Directions for Use]

[POWDER FORM]

[TABLET FORM]



3/11

MASTER LABEL

Front Panel Continued

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- ! Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- ! Remove contact lenses, if present after 5 minutes, then continue rinsing eye.
- ! Call a Poison Control Center or doctor for further treatment advice.

If on Skin:

- ! Take off contaminated clothing.
- ! Rinse skin immediately with plenty of water for 15-20 minutes.
- ! Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- ! Call Poison Control Center or doctor immediately for treatment advice.
- ! Have person sip a glass of water if able to swallow.
- ! Do not induce vomiting unless told to do so by the poison control center or doctor.
- ! Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Net Contents: [0.18 oz. (5 grams), 0.35 oz. (10 grams), 1.44 oz. (40 grams), 1.75 oz. (50 grams), 1.1 lbs. (500 grams), 11 lbs. (5 kilograms)] [See individual product]

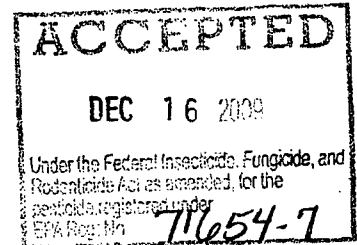
[When dissolved in lukewarm water forms a [16 oz] [32 oz] [1 gallon] [5 quarts][13 gallons][132 gallons] 1% solution]

A 1% solution is stable as a broad spectrum disinfectant for 7 days.

[Use one 5 gram tablet in 16 oz of water to make a 1% solution]

[Use two 5 gram tablets in 32 oz of water to make a 1% solution]

[Use one 40 gram tablet in 1 gallon of water to make a 1% solution]



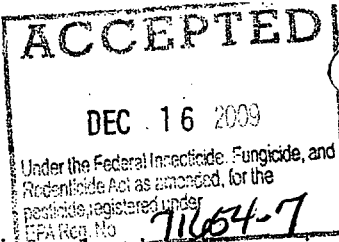
Manufactured for
E. I. Du Pont de Nemours and Company
1007 Market Street
Wilmington, DE 19898
Questions? Call 1-800-441-7515

EPA Reg. No. 71654-7

EPA Est. No. XXXXX

<Lot or batch #>

Virkon is a registered trademark of Antec International Ltd.; US Patent No. 4822512



4
11

MASTER LABEL

DIRECTIONS FOR USE:

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

INSTITUTIONAL, FOOD PROCESSING, AND PUBLIC SERVICE FACILITIES

With VIRKON, only one product is needed to clean and disinfect.

Do Not Use Virkon on acid-sensitive surfaces such as marble or soft metals such as copper, brass, and certain grades of aluminum. Avoid splashing VIRKON solution on textiles or carpets. End-user should assure compatibility of all critical materials that may be contacted by Virkon.

Do not mix product or in-use solution with other chemicals including bleach or other halogen-containing materials.

Cleaning Procedure: Remove gross dirt and prepare a 1.0% solution according to the table below. Apply to surface using a sponge, brush, or spray device, scrubbing as necessary until the surface is visibly clean. Rinse.

Cleaning and Disinfecting Hard Non-porous Food Contact Surfaces: Remove gross dirt and prepare 1.0% solution according to the table below. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Hard Non-porous Non-Food Contact Surfaces: Remove gross dirt and use 1.0% Virkon solution prepared according to the table below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Let stand 10 minutes and air dry. In cases of fungal contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon solution.

This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

Cleaning and Disinfecting, or Sanitizing Manikins Used in CPR Training:

Sanitizing manikins between students:

Prepare a 3% solution of Virkon [according to dilution chart] [by dissolving 3 tablets (5 gm each) of Virkon in one pint [16 oz] water] [by dissolving 1 tablet (5 gm) of Virkon in pre-marked 5.3 oz spray bottle that has been filled to line with water.] Thoroughly spray the manikin surface (mouth and nose area) or wipe with a cloth saturated with 3% solution until fully wetted. Allow surface to remain visibly wet for a minimum of 30 seconds, and wipe with a disposable cloth until dry. Rinse surface with potable water.

Cleaning and Disinfecting manikins after class:

Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Virkon solution. Let stand for 10 minutes and rinse with potable water.

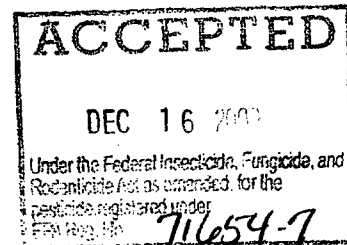
Crisis Scene Disinfection of Hard Non-Porous Surfaces:

For bacterial and viral* control: Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus aureus, Methicillin-Resistant Staphylococcus aureus (MRSA), Vancomycin-Resistant Enterococcus faecalis, (VRE), and Staphylococcus epidermidis.

*Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV (Human Immunodeficiency Virus (HIV-1) (AIDS virus), Influenza A, Respiratory Syncytial Virus (RSV), Norovirus (Norwalk-like viruses), Avian Influenza Virus, Swine Influenza A (H1N1) Virus [OPT], Influenza A (H1N1) Virus [OPT], Influenza A H1N1 Virus [OPT].

Not for use with Medical Instruments.

This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.



6
11

MASTER LABEL

[For [sachet] [pouch] [packet] [bag] packaged with bottle of water: Remove gross dirt. To make a 1% solution, remove cap from bottle of pre-measured water provided. Completely empty entire contents of [sachet] [pouch] [packet] [bag] into the bottle of water provided. Recap bottle and gently shake until powder is dissolved. Remove cap and replace with sprayer. Apply to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

[For tablet packaged with [16 oz][32 oz]bottle of water: Remove gross dirt. To make a 1% solution, remove cap from bottle of pre-measured water provided. Add [one][two] tablet(s) into the bottle. Recap bottle and gently shake until tablet is dissolved. Remove cap and replace with sprayer. Apply to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

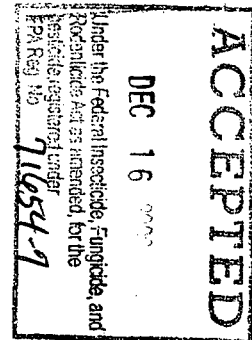
[For [sachet] [pouch] [packet] [bag] packaged with empty bottle: Remove gross dirt. To make a 1% solution, remove cap from empty bottle provided. Fill bottle with water. Completely empty contents of Virkon [sachet] [pouch] [packet] [bag] into the bottle of water, recap bottle, and gently shake until powder is dissolved. Remove cap and replace with sprayer. Apply to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

[For tablet packaged with empty [16 oz][32oz]bottle: Remove gross dirt. To make a 1% solution, remove cap from empty bottle provided. Fill bottle with water. Add tablet into the bottle, recap bottle, and gently shake until tablet is dissolved. Remove cap and replace with sprayer. Apply solution to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

[For a 1% solution from powder: Remove gross dirt. Refer to dilution chart. Fill container with required amount of water and add Virkon powder to achieve solution concentration. Cap container and gently shake until powder is dissolved. Apply solution to surface using a sponge, brush, or spray device until the surface is visibly wet. Let stand for 10 minutes and air dry.]

[For a 1% solution from tablet: Remove gross dirt. Add one 5 gm (0.18 oz) Virkon tablet per pint of water. Cap container and gently shake until tablet is dissolved. Apply solution to surface using a sponge, brush, or spray device until the surface is visibly wet. Let stand for 10 minutes and air dry.]

[To Use for Cleaning and Disinfecting Respirator Face Plates: Disassemble respirator per manufacture's directions for cleaning and disinfection. Remove gross dirt. Refer to Virkon dilution chart. Prepare a 1% Virkon solution by fully dissolving the appropriate amount of Virkon (powder or tablets) in water. Submerge or spray the respirator face plate with a 1% Virkon solution so that the surfaces to be disinfected remain wet for 10 minutes. Rinse thoroughly with water to remove disinfectant. Allow to dry].



2
11

MASTER LABEL

[To Use as an absorbent for blood, body fluids, or vomit: Cover soiled area with Virkon powder. Let stand for 10 minutes and scoop into plastic bag and handle as biohazardous waste. Follow up with a disinfectant step by applying a 1% Virkon solution (prepared according to dilution chart) to surface using a sponge, brush, or spray device until the surface is visibly wet. Let stand for 10 minutes and air dry. Bag containing soil must be disposed of as infectious waste.]

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST *HIV-1, Hepatitis B (HBV), and Hepatitis C (HCV) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

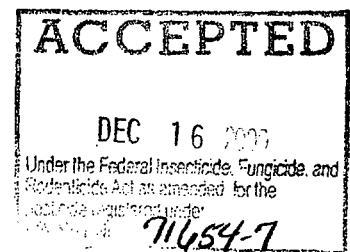
*Kills HIV-1, HBV, and HCV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes, etc.) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects using a cleaner (such as Virkon) before application of this product as a disinfectant. (See previous label instructions for use of Virkon as cleaner.)

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.



8
11

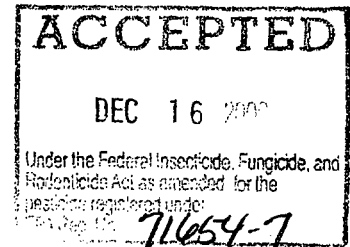
MASTER LABEL

DILUTION CHART

Choose a delivery option from the list below		Add the following amount of Virkon® to the designated volume of water					
		1%					
Virkon®		16 oz. (Pint)	32 oz. (Quart)	128 oz. (Gallon)	160 oz. (5 Quarts)	640 oz. (5 Gallons)	
Metric	Standard						
5 g Tablet	0.18 oz Tablet	1 Tablet	2 Tablets	8 Tablets	10 Tablets	40 Tablets	
40 g Tablet	1.44 oz Tablet			1 Tablet		5 Tablets	
50 g Sachet	1.8 oz Sachet				1 Sachet	4 Sachets	
500 g Shaker Bottle	17.6 oz Shaker Bottle	1 tsp.	2 tsp.	8 tsp.	10 tsp.	40 tsp.	
5 kg Bucket	176 oz Bucket	1 tsp.	2 tsp.	8 tsp.	10 tsp.	40 tsp.	
		2%					
		16 oz. (Pint)	32 oz. (Quart)	128 oz. (Gallon)	160 oz. (5 Quarts)	640 oz. (5 Gallons)	
5 g Tablet	0.18 oz Tablet	2 Tablet	4 Tablets	16 Tablets	20 Tablets	80 Tablets	
40 g Tablet *	1.44 oz Tablet			2 Tablets		10 Tablets	
50 g Sachet	1.8 oz Sachet				2 Sachets	8 Sachets	
500 g Shaker Bottle	17.6 oz Shaker Bottle	2 tsp.	4 tsp.	16 tsp. (1/3 cup)	20 tsp.	1-2/3 cups	
5 kg Bucket	176 oz Bucket	2 tsp.	4 tsp.	16 tsp. (1/3 cup)	20 tsp.	1-2/3 cups	
		3%					
		170 ml (5.75 oz)	16 oz. (Pint)	32 oz. (Quart)	128 oz. (Gallon)	160 oz. (5 Quarts)	640 oz. (5 Gallons)
5 g Tablet	0.18 oz Tablet	1 Tablet	3 Tablet	6 Tablets	24 Tablets	30 Tablets	120 Tablets
40 g Tablet *	1.44 oz Tablet				3 Tablets		15 Tablets
50 g Sachet	1.8 oz Sachet					3 Sachets	12 Sachets
500 g Shaker Bottle	17.6 oz Shaker Bottle		1 Tbsp.	2 Tbsp.	0.5 cups	10 Tbsp.	2-1/2 cups
5 kg Bucket	176 oz Bucket		1 Tbsp.	2 Tbsp.	0.5 cups	10 Tbsp.	2-1/2 cups

[tsp = teaspoon]
[Tbsp = tablespoon]

A 1% solution is effective as a [broad spectrum disinfectant][hospital disinfectant] for 7 days.



11/9

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER: Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear protective clothing and rubber gloves. Wear goggles, face shield, or safety glasses. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement does not refer to 1% in-use solution.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[Note to Reviewer: Effluent discharge statement to be included for package sizes of greater than or equal 5 gallons (liquid) or 50 pounds (solid, dry weight), in accordance with PR Notice 95-1.]

STORAGE AND DISPOSAL

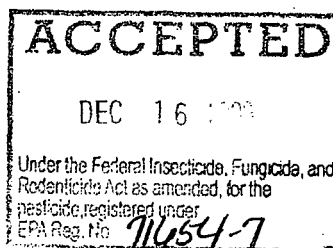
PESTICIDE STORAGE:

For pails, jugs, bottles: Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain dessicant cannister with product during storage.] Do not mix this product with other chemicals.

For [sachet] [pouch] [packet] [bag]: Store in cool dry place. Keep out of reach of children. [Retain dessicant cannister with product during storage.] Do not mix this product with other chemicals.

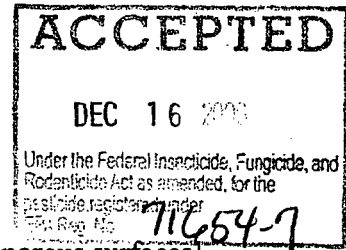
[For spray bottle with in-use solution]: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke



10
11

MASTER LABEL



Note: [Bracketed information is optional text]

DISINFECTANT CLAIMS

- [One step cleaner/disinfectant*]
- [Cleans and disinfects in one step*]
- [Multipurpose disinfectant cleaner for use on inanimate hard non-porous surfaces]
- [Will effectively clean and disinfect when used as directed]
- [Hospital Disinfectant]
- [Broad Spectrum Disinfectant]
- [Effective against Hepatitis A Virus (HAV)]
- [Kills Hepatitis A Virus (HAV)]
- [Effective against Hepatitis B Virus (HBV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]
- [Kills Hepatitis B Virus (HBV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]
- [Effective against Hepatitis C Virus (HCV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]
- [Kills Hepatitis C Virus (HCV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]
- [Effective against Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus [and HIV-1] on pre-cleaned environmental surfaces/objects previously soiled with blood or body fluids].
- [Kills Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus [and HIV-1] on pre-cleaned environmental surfaces previously soiled with blood or body fluids].
- [Effective against Avian Influenza Virus]
- [Kills Avian Influenza Virus]
- [Effective against both Human and Avian Influenza Virus]
- [Kills [more than] 99.9% [bacterial] germs and viruses** (Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus aureus, and Staphylococcus epidermidis)]

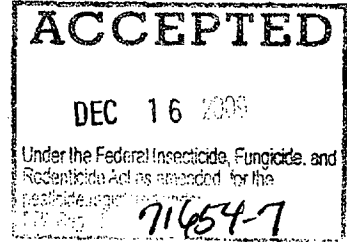
* A pre-cleaning step is necessary for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV (Human immunodeficiency Virus (HIV-1) (AIDS virus)).
 **Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV (Human immunodeficiency Virus (HIV-1) (AIDS virus)).

- [Kills Hepatitis B and HIV (Human Immunodeficiency Virus (HIV- 1) (AIDS virus) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]
- [Kills Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus on pre-cleaned environmental surfaces previously soiled with blood or body fluids]
- [Virucidal], [Bacteriocidal], [Germicidal], [Fungicidal]
- [Kills bacteria and viruses [important to First Responders]: * Hepatitis A (Hepatitis A Virus), Hepatitis B (Hepatitis B Virus), Hepatitis C (Hepatitis C Virus), HIV (Human Immunodeficiency Virus (HIV-1) (AIDS virus) Swine Influenza A (H1N1) Virus [OPT], Influenza A (H1N1) Virus [OPT], Influenza A H1N1 Virus [OPT].
 - [Disinfects respirators]
 - [For disinfecting respirators]
 - [Sanitizes CPR manikins between use]
 - [Efficacious against prevalent hospital pathogens such as MRSA, VRE, RSV]
 - [Efficacious against prevalent foodborne pathogens such as Hepatitis A Virus and E. coli O157:H7]
- Effective against [Norovirus (Norwalk-like viruses)] [MRSA], [VRE], [RSV], [Influenza virus], [Avian Influenza Virus [(H3N2)], [Swine Influenza A (H1N1) Virus] Influenza A (H1N1) Virus [OPT], Influenza A H1N1 Virus [OPT].
 - [Use one tablet per pint of water to make a 1% solution]

11
11

ADDITIONAL MARKETING CLAIMS

- ! [Will not harm most surfaces upon incidental contact]
- ! [Will not harm most hard non-porous surfaces]
- ! [Compatible with most surfaces upon incidental contact]
- ! [Compatible with most hard non-porous surfaces]
- ! [Non-damaging to most surfaces upon incidental contact]
- ! [Non-damaging to most hard non-porous surfaces]
- ! [Safe for most hard non-porous surfaces]
- ! [Pleasant citrus scent]
- ! [Does not compromise the integrity of turnout gear (i.e. Treated Cotton, Aramid fiber, Indura® Ultra-Soft®, PBI, Kevlar®, Lenzing FR®, Tychem®, Polyethylene film coated, Saranex 23P film coated, Sparkguard®, Nomex®, Neoprene)]
- ! [Compliant with OSHA bloodborne pathogen standard]
- ! [Meets NFPA 1581 guidelines]
- ! [Use powder to absorb spills and solution to disinfect]
- [NSF listed]
- [Has NSF listing (D1)]
 - [Fragrance Free]
 - [No dyes or fragrances added]



[Note to reviewer: NSF logo on back or side panel only]



[Note to reviewer: pictograms for optional use with tabletted product]