

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 9, 2021

Abigail T.D. Wacek Senior Regulatory Consultant Medline Industries, Inc. Three Lakes Drive Northfield, IL 60093

Subject: PRIA Label Amendment – Update Label Efficacy Claims and Marketing

Product Name: Micro-Kill Bleach Germicidal Bleach Solution

EPA Registration Number: 37549-2

Received Date: 08/06/2021 Action Case Number: 00218106

Dear Ms. Wacek:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jack Hall by phone at 703-347-8647, or via email at hall.john.j@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

{Administrative Note: Bracketed text [] is optional version of text for different packaging.} {Administrative Note: The following terms may be used interchangeably throughout: "Glucometers", "Glucose Meters" and "Blood Glucose Meter"; "Solution" and "liquid"; "Container", "bottle", "spray bottle", "refillable container" and "refillable spray bottle"; "Bleach", "NaOCl," and "sodium hypochlorite"; "This Product", "These Products", "This solution", and "Product Name"; "0.65%" and "6500 parts per million / ppm"; "Contact time" and "kill time". Terms such as "minute" and "second" may be abbreviated as "min." and "sec." The primary and alternate brand names may be used interchangeably throughout.}

{Sub Label A: Ready to Use Spray Bottle}

# MICRO-KILL BLEACH GERMICIDAL BLEACH SOLUTION [Product Name]

[Alternate Brand Names: Micro-Kill Bleach Solution, Micro-Kill Bleach Germicidal Solution, Micro-Kill Disinfectant Bleach Solution]

This solution is antimicrobial, disinfectant with sporicidal\* activity against *C. diff*, virucidal\*\*, bactericidal, and fungicidal [.] [and can be used for disinfecting hard, non-porous [environmental] [and] [healthcare] surfaces.]

**Active Ingredient:** 

 Sodium hypochlorite.
 0.65%

 Other Ingredients:
 99.35%

 Total.
 100.00%

**ACCEPTED** 04/09/2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 37549-2

SUGGESTED AREAS OF USAGE: [Site(s) from Use Sites Table or surface(s) from Surfaces Table]

# KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID: If in eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have the product container with you when calling a poison control center or doctor, or going for treatment.

[(See [side] [back] panel[s] [on reverse] [of] [outer box] for [additional] directions for use, first aid statement, and additional precautionary statements.)]

OR

[(See [side] [back] panel[s] [of] [on] [the] [reverse] [of] [the] [outer box] [label] for [additional] kill claims, directions for use, suggested areas of usage, first aid statement, special instructions for cleaning and decontamination against +HIV-1, +HBV and +HCV, and special instructions for cleaning and disinfecting against *Clostridium difficile* spores\*, precautionary statements, and storage and disposal.)]

EPA Reg. No. 37549-2

[DIN: #]

EPA Est. No. xxxxx-xx-xxx Net Contents: [x fl. oz.]

[CAT # xxxx]

#### **DIRECTIONS FOR USE**

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

## [HOSPITAL] [HEALTHCARE FACILITY] [GENERAL] DISINFECTION

- 1. Always use personal protective equipment.+
- 2. Open [Product Name] [container]. [Replace the closure with the trigger sprayer.]
- 3. [Spray] [Apply] [Product Name] [bleach solution] on desired surface.
- 4. Visible soil must be removed prior to disinfecting.

{Note: Only one of the two statements will be on the label.}

A 30 second contact time is required [for efficacy against] [to kill] the [organisms] [bacteria and viruses\*\*] on the label except a 1 minute contact time is required [for efficacy against] [to kill] [Candida albicans] [and] [Trichophyton interdigitale] and a 5 minutes contact time is required [for efficacy against] [to kill] Clostridium difficile spores\*. [Reapply] [Spray] [as often] as necessary to ensure that the surface remains visibly wet for the entire contact time.

OR

Allow treated surfaces to remain visibly wet for 5 minutes. [Reapply] [Spray] [as often] as necessary to ensure that the surface remains visibly wet for the entire contact time.

- 5. Scrub and wipe with towel of your choice over desired surface to be disinfected.
- 6. Allow surface to air dry [and discard [used] towel[s]].
- 7. [When container is empty, only] refill [the spray bottle] [only] with [Product Name].
- 8. [To] discard empty container [see STORAGE AND DISPOSAL].

{*Note reviewer: Optional for refill containers*  $\leq 1$  *gallon.*}

# [FOR REFILLING] [TO REFILL] CONTAINERS [SOLD SEPARATELY]

- 1. Always use personal protective equipment. {AND/OR} Wear gloves when handling this product.
- 2. To refill the spray bottle, remove the trigger sprayer of the container to be refilled.
- 3. Open the refill container of [Product Name].
- 4. Pour the solution from the refill container into the refillable container and [then] replace the trigger sprayer on the refilled container and replace the closure on the refill container.
- 5. Refer to [the label on the] refillable container for **DIRECTIONS FOR USE**.

{Administrative Note: If a virucidal claim for HIV-1, HBV, or HCV is made the following paragraph and special instructions are required}

+KILLS HIV-1, HBV, AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids and in which the surfaces/objects likely to be soiled with blood/body fluids can be

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV. AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

associated with the potential for transmission of HIV-1 (associated with AIDS), HBV, and HCV.

- **PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable [protective] [latex] gloves, gown, mask[s] [,] and eye [protection] [coverage].
- **CLEANING PROCEDURE:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before [application of] [applying] [spraying with] [Product Name].
- **CONTACT TIME:** Allow surface(s) to remain wet for 30 seconds to kill the [organisms] [bacteria and viruses\*\*] on the label except a 1 minute contact time is required [for efficacy against] [to kill] [Candida albicans] [and] [Trichophyton interdigitale] and a 5 minute contact time is required [for efficacy against] [to kill] [Clostridium difficile spores\*].

• **DISPOSAL OF INFECTIOUS MATERIAL:** Blood/body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

# \* SPECIAL [LABEL] INSTRUCTIONS FOR CLEANING PRIOR TO DISINFECTION AGAINST *Clostridium difficile* SPORES:

- **PERSONAL PROTECTION:** Wear appropriate barrier protection such as gloves, gowns, masks [and] [or] eye [covering] [protection].
- CLEANING PROCEDURE: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by [applying] [application] [with] [of] [a clean] [cloth], [mop], [and/or] [and] [or] [sponge] saturated with] [Product Name]. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled [cloths/solution] [cloths] [solution] [mop] [and/or] [and] [or] [sponge].
- **INFECTIOUS MATERIALS DISPOSAL:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

This product is not to be used as a terminal sterilant/high level disinfectant 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 barriers or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

<sup>†</sup>This product is for the exterior surfaces of Glucometers and is not for use on the needle and/or the monitors.

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals[.]

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

This product contains bleach. Do not use this product with other chemicals such as ammonia, toilet bowl cleaners, rust removers, or acid, as this releases hazardous gases.

# STORAGE AND DISPOSAL Do not contaminate water, food, or feed by storage or disposal

**Pesticide Storage**: Store in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

**Product Disposal**: Products or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

# **Container Handling And Disposal:**

A. [For Household/Residential Products]

[For rigid nonrefillable container less than 5 gallons]

**Container Handling:** Nonrefillable rigid container. Do not re-use or refill this container. Triple rinse (or equivalent), promptly after emptying. Offer for recycling, if available, or throw in trash.

# B. [For Commercial/Industrial/Institutional Products]

[For rigid nonrefillable container less than 5 gallons]

**Container Handling:** Nonrefillable rigid container. Do not re-use or refill this container. Triple rinse (or equivalent), promptly after emptying. 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.

#### *C.* [For refillable containers]

Container Handling: Refillable containers. Refill this container with [Product Name] only. Do not reuse this container for any other purpose. To clean the container before final disposal: Triple rinse (or equivalent), promptly after emptying. 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.

Medline logo Medline Industries, Inc. Three Lakes Drive Northfield, IL 60093 Medline website Medline barcode

For product emergency, contact: Poison Control Center, 1-800-222-1222

For Technical Information call: 1-800-MEDLINE

For an SDS, call 1-800-MEDLINE and request document [Document ID Number]

# [Efficacy Claims]

#### \*SPORICIDAL / SPORES 5 minute[s] contact time

• Clostridium difficile [C. difficile] [C. diff] [C DIFF] spores\* [ATCC 43598]

# \*\*VIRUCIDAL / VIRUSES 30 second[s] contact time [SMALL NON-ENVELOED VIRUSES]

- Canine Parvovirus [ATCC VR-2017]
- Enterovirus [Type] D68 (Strain US/KY/14-18953) [ATCC VR-1825]
- Feline Panleukopenia Virus [Feline parvovirus] [ATCC VR-648]
- Hepatitis A Virus [(]HAV[)] [HM-175]
- Norovirus (Feline Calicivirus) [Norwalk Virus] [ATCC VR-782]
- Polio Virus (Type 1) [ATCC VR-1562]
- Rhinovirus (Type 37) [ATCC VR-1147]

#### [LARGE NON-ENVELOPED VIRUSES]

- Adenovirus Type 5 [Adenovirus] [ATCC VR-5]
- Rotavirus [ATCC VR-2018]

#### [ENVELOPED VIRUSES]

- Avian Influenza A Virus (H3N2) [ATCC VR-2072]
- Avian Influenza A Virus (H5N1) [CDC 2006719965]
- Avian Influenza A Virus (H7N9) [CDC 2013759189]
- Cytomegalovirus [CMV] (Strain AD-169) [ATCC VR-538]
- Herpes Simplex Virus Type 2 [(]HSV-2[)] [ATCC VR-734]
- Human Coronavirus [ATCC VR-740]
- Influenza A Virus (H1N1) [CDC 2009712192]
- Influenza A Virus [ATCC VR-544]
- Influenza B Virus (Strain B) [ATCC VR-823]
- Respiratory Syncytial Virus [(]RSV[)] [ATCC VR-26]
- SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020]

# [ENVELOPED VIRUSES] [BLOODBORNE PATHOGENS]

- +Hepatitis B Virus [(DHBV)] [(]HBV[)]
- +Hepatitis C Virus [(BVDV)] [(]HCV[)]
- +Human Immunodeficiency Virus Type 1 [(]HIV-1[)] [HTLV-IIIB] [Aids Virus]

#### [ANIMAL VIRUSES]

- Bovine Viral Diarrhea Virus (BVDV) (HCV)
- Duck Hepatitis B Virus (DHBV) (HBV)
- Feline Calicivirus (ATCC VR-782)

#### BACTERICIDAL / BACTERIA 30 second[s] contact time

- Acinetobacter baumannii MDR [(]A. baumannii-MDR[)] [Multidrug resistant [(MDR)] [Acinetobacter baumannii] [A. baumannii]] [MDR [(Multidrug resistant)] [Acinetobacter baumannii] [A. baumannii]] [ATCC 19606]
- Bordetella pertussis [(]B. pertussis[)] [ATCC 12743]
- Campylobacter jejuni [(]C. jejuni[)] [ATCC 29428]

- [Community Acquired] [CA-] Methicillin Resistant *Staphylococcus aureus* [Genotype USA400] [CA-MRSA] [NRS 123]
- Enterobacter aerogenes [(]E. aerogenes[)] [ATCC 13048]
- Enterobacter cloacae [(]E. cloacae[)] [ATCC 13047]
- [Enterococcus faecalis –VRE] [ATCC 51575] [Vancomycin-Resistant Enterococcus faecalis] [(]VRE[)]
- Enterococcus faecium-MDR [(E. faecium-MDR)] [Multidrug resistant [(MDR)] [Enterococcus faecium] [E. faecium] [MDR [(Multidrug resistant)] [Enterococcus faecium] [E. faecium] [ATCC 51559]
- Escherichia coli [(]E. coli[)] [ATCC 11229]
- Escherichia coli O157:H7 [(]E. coli O157:H7[)] [ATCC 35150]
- Escherichia coli-ESBL [ESBL] [(Extended Spectrum Beta-Lactamase)] producing [Escherichia coli] [(]E. coli[)] [Extended Spectrum Beta-Lactamase [(ESBL)] producing [Escherichia coli] [(]E coli[)] [ATCC BAA-196]
- Escherichia coli-NDM-1 [(]E. coli-NDM-1[)] [[Escherichia coli] [(E. coli)] [New Delhi Metallo-Beta-Lactamase-1] [(NDM-1)]] [[NDM-1 [Escherichia coli] [(]E. coli[)]] [CDC 1001728]
- *Klebsiella pneumoniae* [(]*K. pneumoniae*[)] [ATCC 4352]
- Klebsiella pneumoniae-CRKP [(]CRE[)] [(] [Carbapenem resistant Enterobacteriaceae] [)] [(CRE)] [Carbapenem resistant Klebsiella pneumoniae [(CRKP)] [ATCC BAA-1705] {Note to reviewer: The following statement is required with use of CRE Klebsiella pneumoniae is a member of the family Enterobacteriaceae.}
- *Klebsiella pneumoniae*-ESBL [ESBL [(Extended Spectrum Beta-Lactamase)] producing [*Klebsiella pneumoniae*] [(]*K. pneumoniae*[)] [Extended Spectrum beta-Lactamase [(ESBL)] producing [*Klebsiella pneumoniae*] [(]*K. pneumoniae*[)] [ATCC 700603]
- *Klebsiella pnuemoniae*-NDM-1 [(]*K. pneumoniae*-NDM-1[)] [[*Klebsiella pneumoniae*] [(]*K. pneumoniae*[)] [New Delhi Metallo-Beta Lactamase-1] [(]NDM-1[)] [[NDM-1 [*Klebsiella pneumoniae*] [(]*K. pneumoniae*[)] [CDC 1000527]
- Legionella pneumophila [(]L. pneumophila[)] [(]Legionella[)] [ATCC 33153]
- Linezolid Resistant *Staphylococcus aureus* [(]LRSA[)] [NRS 119]
- Listeria monocytogenes [(]L monocytogenes[)] [(]Listeria[)] [ATCC 19117]
- Methicillin Resistant *Staphylococcus aureus* [(]MRSA[)] [ATCC 33592]
- *Proteus mirabilis* [(]*P. mirabilis*[)] [ATCC 9240]
- Pseudomonas aeruginosa [(]P. aeruginosa[)] [ATCC 15442]
- Salmonella enterica [ATCC 10708]
- *Serratia marcescens* [ATCC 14756]
- *Shigella dysenteriae* [ATCC 11835]
- Staphylococcus aureus [ATCC 6538]
- Staphylococcus aureus-VISA [ATCC HIP 5836] [Vancomycin-Intermediate Staphylococcus aureus] [VISA]
- Staphylococcus aureus –VRSA [VRS1] [Vancomycin-Resistant Staphylococcus aureus] [VRSA]
- Streptococcus pneumoniae [ATCC 6305]
- *Streptococcus pyogenes* [ATCC 19615]

#### FUNGICIDAL / FUNGI 1 minute contact time

- Candida albicans [(]C. albicans[)] [ATCC 10231]
- Trichophyton interdigitale [(Organism that causes Athlete's Foot Fungus)] [ATCC 9533]

For use on hard non-porous, nonfood contact surfaces in the following Use Sites: {Note to reviewer: These sites to be used where indicated in claims.}			
- Bathrooms	- Hospitals	<ul> <li>Physician offices</li> </ul>	
- Cafeterias	- ICU/CCU	<ul> <li>Police stations</li> </ul>	
<ul><li>Clinical laboratory[ies]</li></ul>	- ISO9000 environments	<ul><li>Poultry houses</li></ul>	
[lab[s]	- Kitchens	<ul> <li>Recovery room</li> </ul>	
<ul><li>Cruise ships</li></ul>	<ul> <li>Laboratories</li> </ul>	<ul> <li>Rehabilitation facilities</li> </ul>	
<ul><li>Dental laboratory[ies] [lab[s]</li></ul>	<ul><li>Medical laboratory[ies]</li></ul>	- Restaurants	
<ul> <li>Dental offices</li> </ul>	[lab[s]	- Schools	
<ul> <li>Doctor's Offices</li> </ul>	<ul><li>Mortuaries</li></ul>	<ul> <li>Skilled long term care</li> </ul>	
<ul> <li>Emergency Rooms</li> </ul>	<ul> <li>Nursery schools</li> </ul>	facility[ies]	
<ul> <li>Extended care facilities</li> </ul>	<ul><li>Nursing homes</li></ul>	<ul> <li>Skilled Nursing Facility</li> </ul>	
<ul><li>Farm premises</li></ul>	<ul> <li>Nursing stations</li> </ul>	(SNF)	
<ul><li>Fire stations</li></ul>	- Offices	<ul> <li>Veterinarian clinics/hospitals</li> </ul>	
<ul><li>Hospital laboratory[ies]</li></ul>	<ul><li>Physical therapy</li></ul>		
[lab[s]	facilities/offices		

For use on hard, non-porous, nonfood contact of the following Surfaces Table:				
{Note to reviewer: These surfaces to be used where indicated in claims.}				
<ul> <li>[Blood] glucose meters†</li> </ul>	_	Exam tables	_	Plastics
<ul> <li>[Hard] plastic surfaces</li> </ul>	_	Flush handles	_	Plexiglas
<ul> <li>Ambulance equipment</li> </ul>	_	Food contact surfaces	_	Point-of-care equipment
<ul> <li>Bar code readers</li> </ul>	_	Formica	_	Room temperature control
<ul> <li>Bathroom handrails</li> </ul>	_	Glass		knobs
<ul><li>Bed pan[s]</li></ul>	_	Glazed [ceramic] tiles	_	Salad bar surfaces
<ul><li>Bed rails</li></ul>	_	Glazed porcelain	-	Shower head control knobs
<ul> <li>Bedside commodes</li> </ul>	_	Glucometers†	-	Sink tops
<ul> <li>Bedside tables</li> </ul>	_	Infusion pumps	_	Soft drink dispenser surfaces
<ul> <li>Bedside testing equipment</li> </ul>	_	Instrument stands	_	Sphygmomanometers
<ul> <li>Biological safety</li> </ul>	_	IV pole	_	Stainless steel
cabinets/hoods	_	Keyboards	-	Stretchers
- Cables	_	Laboratory counters	-	Table tops
- Carts	_	Laminated [plastic]	-	Telemetry equipment
<ul> <li>Cell phones</li> </ul>		countertops	_	Telephones
- Chair[s]	_	Light switches	_	Toilet bedpan cleaner
<ul><li>Clean rooms</li></ul>	_	Medical counters	-	Toilet seats
<ul><li>Computer screen[s]</li></ul>	-	Mobile phones	_	Touch screens
<ul><li>Computer keyboard[s]</li></ul>	_	Multi-module monitor	_	Trash cans
<ul><li>Countertops</li></ul>		controls/touch screens/cables	_	Tray table
<ul> <li>Dental counters</li> </ul>	_	Patient bed controls	_	Ventilator control panel
<ul> <li>Diagnostic equipment</li> </ul>	_	Patient care equipment	_	Veterinary medicine
<ul> <li>Dialysis machines</li> </ul>	_	Patient monitoring	_	Vinyl and surfaces
<ul><li>Digital phones</li></ul>		equipment	_	Water control knobs
<ul> <li>Digital screens</li> </ul>	_	PVC tubing (exterior	_	Wheel chairs
<ul><li>Door knobs</li></ul>		surfaces)	_	Wireless phones
<ul><li>Door levers</li></ul>	_	Pharmaceutical exhaust		
<ul><li>Drawer pull[s]</li></ul>		hoods		
Electronic digital equipment	_	Phone and call button		C

1 .	<b>nfood contact of the following Sur</b> <i>to be used where indicated in claim.</i>	
Equipment [and monitors]     with digital screens	Plastic mattress covers	

Stains Table		
{Note to reviewer: These s	tains/soils to be used where indicated i	in claims.}
- Blood	- Grease	<ul> <li>Organic matter</li> </ul>
<ul> <li>Coffee stains</li> </ul>	- Grime	- Tea stains
– Dirt	<ul> <li>Laboratory stains</li> </ul>	– Urine
<ul> <li>Fecal matter</li> </ul>	<ul> <li>Common soils</li> </ul>	
<ul><li>Fingerprints</li></ul>	<ul> <li>Common stains</li> </ul>	

# **Claims Against Emerging Viral Pathogens**

{[Product Name] qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions.}

[Product Name] meets the criteria to make the claims against certain emerging viral pathogens from the following viral categories:

- Enveloped viruses
- Large non-enveloped viruses
- Small non-enveloped viruses

For an emerging viral	follow the directions for use for the following organisms on the	
pathogen that is a/an	label:	
Enveloped virus	Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]	
Large, non-enveloped virus	Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]	
Small, non-enveloped virus	Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]	
	Rhinovirus [Type 37] [ATCC VR-1147]	

#### Acceptable claim language:

- [Product Name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [Product Name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hardnon-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.
- [Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hardnon-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

# **{OPTIONAL ADDITIONAL TEXT FOR USE ON PRODUCT LABEL OR COLLATERAL** LABELING}

- A potable water rinse is required for food contact surfaces.
- A 5 minute contact time is required for use against *Clostridium difficile* spores\*.
- A 1 minute contact time is required for fungicidal use.
- A 30 second contact time is required for *virucidal\*\* and bactericidal* uses.
- Active ingredient in bleach detected at 0.65% Aids [in reducing] [in the reduction of] cross contamination between treated surfaces.
- Aids in reducing cross contamination between treated surfaces.
- All of the [raw materials] [components] of [Product Name] [,] [including the] container and spray device are made in the U.S.A.
- Always refer to the manufacturer's instructions for cleaning and disinfection of the equipment or device before using [Product Name] [on it].
- Antibacterial [solution]
- Antimicrobial [solution]
- Assembled for [and distributed by]: [Company Name]
- Available exclusively from [:] [Company Name]
- Avoid excessive heat.
- Avoid prolonged freezing.
- Avoid direct sunlight.
- Available chlorine equivalent to 0.65%
- Bactericidal
- Bactericide
- Bathroom [disinfectant] solution pre-diluted to 0.65% bleach, is RTU for use on hard, non-porous [environmental] surfaces.
- Bleach [disinfectant] [germicidal] solution[s].
- [Bleach solution] [is] [prediluted to] 0.65% bleach for hospital use.
- [Bleach solution] is [RTU] for hospital use.
- [Bleach] [disinfectant] solution for use on hard, non-porous [healthcare] [,] [and] [environmental] surfaces].
- Broad spectrum disinfectant solution.
- Can be used to clean {and/or} deodorize [and disinfect] [s] hard, non-porous [healthcare] [and] [environmental] [surfaces] in one-step^.
- [Can be used on] [Use on] hard, non-porous surfaces only.
- [Can be used] [For use] to disinfect hard, non-porous surfaces of] [glucometer[s]<sup>†</sup>] [,] [and] [,] [stethoscopes] [and] [sphygmomanometers] [in glucometer<sup>†</sup> rental programs].
- Check with your sales representative for updates in your state.
- Complete product line information available by [calling xxx-xxx-xxxx] [contacting xxx-xxx-xxxx].
- [Can be used to] [For use to] [Disinfect[s] hard, non-porous [environmental] [and] [healthcare] surfaces].
- [Can be used to] [use to] disinfect [Surface(s) from Surfaces Table].
- [Can be used on] [For use on] [Glucometers<sup>†</sup>].
- Carbapenem Resistant Klebsiella pneumoniae is a member of the family Enterobacteriaceae [(]CRE[)].
- Carbapenem Resistant *Klebsiella pneumoniae* [(CRKP)] [or] [-] [(CRE).
- Catalog number

- Cleans, disinfects, and deodorizes.
- Contains solution of 0.65% [available chlorine] [active] [sodium hypochlorite]
- Convenient, disposable solution.
- Cost Savings[:]
- Contact Time: 5 minutes for *Clostridium difficile* spores\*.
- Contact Time: 1 minute for Candida albicans and Trichophyton interdigitale.
- Contact Time: 30 seconds for *virucidal\*\* and bactericidal* uses.
- Date Opened: xx/xx/[xx]xx [Good for 30 days [once opened]]
- Date for Disposal: xx/xx/[xx]xx [30 days after opened].
- Disposable [germicidal] [antimicrobial] [disinfectant with sporicidal\* activity against *C. diff.*] [virucidal\*\*] [bactericidal] [fungicidal] solution.
- Disinfectant
- Disinfects
- Disinfecting
- Disinfects, cleans, deodorizes
- Disinfects hard, non-porous healthcare surfaces [including] [such as] [Surface(s) from Surfaces Table].
- [Disinfectant] [Disinfecting] [bleach] [solution].
- Disinfects [glucometer<sup>†</sup>] [,] [and] [patient care equipment] [,] [and] [point-of-care equipment] and hard, non-porous healthcare surfaces.
- Disinfects [Surface(s) from Surfaces Table] and hard, non-porous healthcare surfaces [including [Surface(s) from Surfaces Table].
- Disinfecting solution that is for use on hard, non-porous surfaces, [glucometer<sup>†</sup>], patient care equipment and point-of-care equipment.
- Disinfects and deodorizes by killing germs and their odors on [Surface(s) from Surfaces Table].
- Distributed by [:] [Company Name]
- Disposable [solution]
- Do not use on glassware, utensils or dishes.
- Do not use [Product Name] [for personal cleansing] [as a skin] [cleaner] [or] [,] [sanitizer] [or] [disinfectant].
- Easy and convenient to use.
- [Easy] [,] [Product Name] [can be used] [as a] [is a] one-step^ cleaner and disinfectant bleach solution[s].
- Each [bottle] [container] of [Product Name] contains [x fl. oz.] [x gallon[s]] [of] [RTU] 0.65% bleach solution.
- Each [1] [one] [case] contains [X] [x fl. oz. bottles] [x gallon bottles] [of] [RTU] 0.65% bleach solution.
- Effective disinfection at your convenience when used per label directions.
- Effective disinfection of hard-to-kill microorganisms listed on label on hard, non-porous surfaces when used per label directions.
- Effective against [bacteria] [germs] [viruses\*\*] [fungi] [spores\*] when used per label directions.
- Effective against SARS-CoV-2 [USA-WA1/2020] [in 30 seconds] on hard, non-porous surfaces.
- [Effective against] [Disinfects] [Kills] [99.999%] SARS-CoV-2 [virus] on hard, non-porous surfaces.
- [Effective against] [Disinfects] [Kills] [99.999%] SARS-CoV-2 virus, the cause of COVID-19 on hard, non-porous surfaces.
- [Eliminates] [or] [reduces odors caused by germs].

- Ensure that the surface remains visibly wet for the entire contact time.
- Equivalent to 1:10 dilution of 6.5% bleach
- [Expiration date] [EXP] [EXP DATE] [XXXXXX]
- For use in [disinfecting] [cleaning] [blood containing body fluids] [blood and body fluid spills] on hard non-porous surfaces.
- Formulated for [cleaning and disinfecting] in [just] one-step.^
- For complete product line information, call [Company Name].
- For cleaning and disinfecting [when] [if] *Clostridium difficile* spores\* are [likely] [to be present] [of concern].
- For refilling [Product Name]
- For surfaces that may come in contact with food, a potable water rinse in required. Do not use on glassware, utensils, or dishes.
- For product questions, call [name and phone number].
- For use in [cleaning and] disinfecting [after remove of fecal contamination] on pre-cleaned hard, non-porous [high touch] [objects] [and] [environmental] [and] [healthcare] [surfaces].
- For use on hard, non-porous [environmental] [and] [healthcare] surfaces.
- For use in the [area] [center] [station] [department] [s] listed [below] [here] [:] [Site(s) from Use Sites Table] [Surface(s) from Surfaces Table].
- For [kitchen] surfaces that may come in contact with food, a potable water rinse in required. Do not use on glassware, utensils, or dishes.
- For food contact surfaces, a potable water rinse is required. Do not use on glassware, utensils, or dishes.
- For use [in] [on] [the] [Site(s) from Use Sites Table] [Surface(s) from Surfaces Table].
- For use on [the] [Site(s) from Use Sites Table] [Surface(s) from Surfaces Table].
- For use on hard, non-porous surfaces that require the use of bleach for disinfecting, cleaning and maintenance.
- For use on bathroom surfaces.
- For daily use in discharge cleaning in healthcare facilities.
- Fresh bleach scent
- Fungicidal solution
- Fungicide
- Fungicidal
- Germicidal [disposable] solution
- Germicidal
- Germicide
- Gloves must be worn
- Help[s] reduce the spread of germs on treated, hard, non-porous surfaces.
- Helps reduce risks of cross-contamination and transmission of microorganisms listed on label on treated, hard, non-porous surfaces and [medical] equipment.
- If streaking is observed after disinfecting for the appropriate contact time, wipe with a clean, damp cloth or paper towel.
- Innovative healthcare products designed with a commitment to quality and excellence.
- Kills Influenza A Virus, commonly knowns as Pandemic 2009 (H1N1).

- Kills Influenza A Virus commonly known as swine flu (H1N1).
- Kills up to 99.9999% of tough to kill *Clostridium difficile* spores\* on hard, non-porous healthcare surfaces.
- Kills 99.99% of germs
- Kills [bacteria] [germs] [viruses\*\*] [fungi] [spores\*]
- Kills *C. diff.* spores\* in 5 minutes.
- Kills SARS-CoV-2 [(coronavirus)] that causes COVID-19 on hard, non-porous surfaces.
- [Kills] [Effective against] the SARS-CoV-2 virus that causes COVID-19 on hard, non-porous surfaces.
- [Kills] [Eliminates] 99.999% SARS-CoV-2 [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19] on hard, non-porous surfaces.
- Kills [99.999% of] SARS-CoV-2 [virus] on hard, non-porous surfaces.
- Kills SARS-CoV-2 [in 30 seconds] on hard, non-porous surfaces.
- Kills SARS-CoV-2 [in one step] on hard, non-porous surfaces.
- Kills odor-causing [bacteria] [germs]
- *Klebsiella pneumoniae* is a member of the family *Enterobacteriaceae*.
- Leaves a fresh bleach scent.
- [Lot Number] [Lot xxxxxx]
- Made in [the] U.S.A.
- Manufactured for [:] [Company Name]
- [Manufactured] [and] [Distributed] [Sold] in the U.S.A.
- Meets surface disinfect recommendation for OSHA blood borne pathogen standard
- Meets efficacy standards for hospital disinfection.
- [No mixing] [No measuring] necessary.
- Not for sale or use after [date].
- Now kills {Note to reviewer: to be used with new efficacy claim limited to 6 months of marketing.}
- Now effective against [organism name] when used per label directions. {Note to reviewer: to be used with new efficacy claim limited to 6 months of marketing.}
- One-step^ [cleaner [and] disinfectant] bleach solution[s].
- One-step^ [antimicrobial] disinfectant with sporicidal\* activity against *C. diff.*] [virucidal\*\*] [bactericidal] [fungicidal] [disinfectant] bleach solution.
- One-step^ [cleaner [and] disinfectant] [disinfectant [and] cleaner] [cleaning [and] disinfecting] bleach solution[s] that [is] [are] disinfectant with sporicidal\* activity against *C. diff.*] [virucidal\*\*]' [bactericidal] [and] fungicidal].
- [Packaged] [Packed] for [XXXXXXX]
- Penetrates and breaks down [dust mite particles] [,] [cockroach particles] [and] [pet dander] [allergens] [found in dust].
- Pre-clean prior to disinfecting hard, non-porous surfaces for [+HCV], [+HBV], [and] [+HIV-1] [and] [Clostridium difficile spores\*].
- [Product Name] [kills] [has demonstrated effectiveness against] [Influenza A viruses including [Pandemic 2009 H1N1 [(formerly called Swine Flu)]] [and] [Influenza A Virus] when used per label directions.
- [Product Name] [is] [are] [a] [one-step^] cleaner and disinfectant [bleach] solution [s].

- [Product Name] kills [Clostridium difficile spores\*] [VIRUSES\*\*, BACTERIA and FUNGI FROM LISTSI.
- [Product Name] kills Avian Influenza A Virus (H3N2), (H5N1) and (H7N9) on hard, non-porous surfaces in poultry house[s] [farm premises].
- [Product Name] tested according to AOAC efficacy testing methods for hospital disinfection.
- [Product Name] [is] [a] [are] for use on hard, non-porous [environmental] surfaces [in] [on] [Surface(s) from Surfaces Table] [Site(s) from Use Sites Table]
- [Product Name] [is a] pre-diluted bleach solution for use on hard, non-porous [healthcare] [and] [environmental] surfaces where control of cross contamination is required [on treated surfaces].
- [Product Name] Meets efficacy standards for hospital disinfection.
- [Product Name] can be used to clean and disinfect in one-step^[:] [,] see directions for use [on this label] for cleaning and disinfecting in one-step^.
- [Product name] has a 2 year shelf life if unopened.
- [Product name] is shelf stable [for up to 2 years if unopened].
- [Product Name] is easy to use.
- [Product Name] is used [as] [for] [to]
- [Product Name] is a one-step^ cleaner and disinfectant solution.
- [Product Name] is [antimicrobial] disinfectant with sporicidal\* activity against C. diff.] [bactericidal] [fungicidal] [virucidal\*\*].
- [Product Name] disinfects glucometers<sup>†</sup>, patient care equipment, point-of-care equipment, and hard non-porous surfaces [such as] [Surface(s) from Surfaces Table].
- [Product Name] is designed to save time and money by not having to mix the bleach solution.
- [Product Name] [is a solution that] contains 0.65% bleach.
- [Product Name] [bleach] [solution] [can be used by [paramedics] [policeman] [firemen] [veterinarians] to disinfect hard, non-porous [environmental] [and] [healthcare] surfaces].
- The [Product Name] [bleach] solution was specifically [designed] [created] to disinfect [Glucometers<sup>†</sup>] and [point of care] [bedside testing]] [equipment] [and] [patient care equipment] [to meet] [to comply with] [the equipment manufacturers maintenance [requirements] [protocols] [procedures].
- [Product Name] [EPA Registration Number 37549-2] [and] [has a] [with a] Clostridium difficile spore\* kill claim with a 5 minute contact time. [Product Name] may not [yet] be available in all 50 states [and Puerto Rico]]. [Please check with your sales representative for updates in your state.]
- [Product Name] [EPA Registration Number 37549-2] [and] [has] [with] [a] [kill] [efficacy] claim[s] for [VIRUS\*\* FROM LIST] [kill] [efficacy] claim[s] with a 30 second contact time[.] [Product Name] may not [yet] be available in all 50 states [and Puerto Rico]]. [Please check with your sales representative for updates in your state.]
- [Product Name] [EPA Registration Number 37549-2] [and] [has] [with] [a] [kill] [efficacy] claim[s] for [BACTERIA FROM LIST] [kill] [efficacy] claim[s] with a 30 second contact time[.] [Product Name] may not [yet] be available in all 50 states [and Puerto Rico]]. [Please check with your sales representative for updates in your state.]
- [Product Name] [EPA Registration Number 37549-2] [and] [has] [with] [a] kill] [efficacy] claim[s] [for] [FUNGUS FROM LIST] [kill][efficacy] claim[s] with a 1 minute contact time[.] [Product Name] may not [yet] be available in all 50 states [and Puerto Rico]]. [Please check with your sales representative for updates in your state.]
- [Product Name] [can be used] [to] [clean] [and] [deodorize] [and] [to] [disinfect].
- [Product Name] is a cleaner disinfectant that kills [Blood borne pathogen[s] [(BBP)]] [BBP] [+HIV-1, +HBV and +HCV].
- [Product Name] [is a] [cleaner disinfectant] [that kills] [blood borne pathogens [(BBP)]] [BBP] [+HIV-1, +HBV and +HCV] on hard, non-porous surfaces.

- [Product Name] [is a] [cleaner disinfectant].
- [Product Name] [can be used to] [clean[s] and disinfect[s]] hard, non-porous [medical equipment surfaces].
- [Product Name] cleans, deodorizes and disinfects in one-step^.
- [Product Name] kills *Clostridium difficile* spores\* in 5 minutes.
- [Product Name] cleans and disinfects hard, non-porous [environmental] [and] [healthcare] surfaces.
- [Product Name] [is] [are] not for [use on] [cleaning] [or] [,] [sanitizing] [or] [disinfecting] skin.
- [Product Name] contains bleach
- [Product Name] can be used on glucometers<sup>†</sup>.
- [Product Name] [is a] one-step^ [multipurpose, broad spectrum] bleach disinfectant [solution] that kills pathogens.
- [Product Name] [can be used] [use as directed] [as a one-step^ disinfectant on pre-cleaned hard, non-porous surfaces] [to disinfect] [for disinfecting] against bloodborne pathogens.
- [Product Name] is used [as] [for] [to]
- [Product Name] it is used [as] [for] [to]
- [Product Name] is a disinfectant with sporidical\* activity against *C. diff* bleach solution cleaner, deodorizer, and disinfectant.
- [Product Name] is a bactericidal bleach solution cleaner, deodorizer, and disinfectant.
- [Product Name] is a fungicidal bleach solution cleaner, deodorizer, and disinfectant.
- [Product Name] is a virucidal\*\* bleach solution cleaner, deodorizer, and disinfectant.
- [Product Name] is an antimicrobial bleach solution cleaner, deodorizer, and disinfectant.
- [Product Name][is][are][antimicrobial product[s]][disinfectant[s]][with label claims for Avian [(Bird)] Flu[.]
- [Product Name] [is] [a] [are] [Germicidal] [Germicide] [bleach] [solution[s]
- [Product Name] [is] [a] [are] [stabilized] [bleach] [solution[s]]
- [Product Name] [is] [a] [are] [virucidal\*\*] [bleach] [solution[s]]
- [Product Name] [is] [an] [are] [Antimicrobial] [bleach] [solution[s]]
- [Product Name] [is] [an] [are] [Antibacterial] [bleach] [solution[s]]
- [Product Name] [is] [a] [are] [Bactericidal] [bleach] [solution[s]]
- [Product Name] [is] [a] [are] [fungicidal] [bleach] [solution[s]]
- [Product Name] [is] [a] [are] disinfectant with sporicidal\* activity against *C. diff.*] [bleach] [solution[s]]
- [Product Name] [is a] [are] [Bleach] [disinfectant] [disinfecting] solution[s].
- [Product Name] [is] [a] [an] [are] [Ready to Use] [hospital disinfectant] [sporidical\*, virucidal\*\*, bactericidal, fungicidal, antimicrobial] [bleach] [solution].
- [Product Name[s]] contain[s] 0.65% [of] [active] [bleach] [available chlorine].
- [Product Name] can be used as a bleach solution for cleaning, deodorizing, and disinfecting and [kills] 99.9999% of [tough to kill] *Clostridium difficile* spores\* in 5 minutes in the presence of organic soil after pre-cleaning on hard, non-porous environmental and healthcare surfaces.
- [Product Name] can be used to clean, deodorize, and disinfect and kills 99.9999% of [tough to kill] *Clostridium difficile* spores\* in 5 minutes in the presence of organic soil after pre-cleaning on hard, non-porous environmental and healthcare surfaces.
- [Product Name] is a [easy to use] [Ready to Use] [as a] sporidical\* bleach solution cleaner, deodorizer, and disinfectant and kills 99.9999% of [tough to kill] *Clostridium difficile* spores\* in 5 minutes in the presence of organic soil after pre-cleaning on hard, non-porous environmental and healthcare surfaces.

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- [Product Name] can be used [as a bleach solution] for cleaning, deodorizing, and disinfecting that kills VIRUS\*\*/BACTERIA FROM LISTS in 30 seconds in the presence of organic soil on hard, non-porous environmental and healthcare surfaces.
- [Product Name] is an [easy to use] [Ready to Use] [as a] virucidal\*\* and bactericidal bleach solution cleaner, deodorizer, and disinfectant that kills **VIRUS**\*\*/**BACTERIA FROM LISTS** in 30 seconds in the presence of organic soil on hard, non-porous environmental and healthcare surfaces.
- [Product Name] can be used as a bleach solution for cleaning, deodorizing, and disinfecting that kills **FUNGI FROM LIST** in 1 minute in the presence of organic soil on hard, non-porous environmental and healthcare surfaces.
- [Product Name] is an [easy to use] [Ready to Use] [as a] fungicidal bleach solution cleaner, deodorizer, and disinfectant that kills **FUNGI FROM LIST** in 1 minute in the presence of organic soil on hard, non-porous environmental and healthcare surfaces.
- [Product Name] [is] [are] disinfectant with sporicidal\* activity against *C. diff.*, virucidal\*\*, bactericidal and fungicidal and can be used to clean, deodorize and disinfect [in one-step^] hard, non-porous [healthcare] [and] [,] [environmental] [surfaces] [Site from Use Site Table] [in one-step^].
- [Product Name] kill[s] [the] [following] multidrug resistant (MDR) gram negative [bacterium] [bacteria] [Acinetobacter baumannii-MDR] [and] [Enterococcus faecium-MDR].
- [Product Name] kill[s] [the] [following] Extended Spectrum Beta-Lactamase (ESBL) producing gram negative [bacterium] [bacteria] [Escherichia coli-ESBL] [and] [Klebsiella pneumoniae]-ESBL].
- [Product Name] kill[s] [the] [following] New Delhi metallo-beta-lactamase (NDM-1) producing gram negative [bacterium] [bacteria] [Escherichia coli-NDM-1] [and] [Klebsiella pneumoniae]-NDM-1].
- [Product Name] contain 0.65% bleach.
- Proper concentration of bleach delivered [every time] for surface disinfection and maximum coverage.
- Protect from freezing.
- Proven to kill SARS-CoV-2, the virus that causes COVID-19, on hard, non-porous surfaces.
- [Pre-mixed] [pre-diluted] [ready-to-use] 0.65% [bleach solution].
- [Ready to Use] [RTU]
- [Ready to Use] [pre-diluted] hospital [use] disinfectant.
- [Ready to use] [pre-diluted] hospital disinfectant.
- [Ready to use] [pre-diluted] hospital [use] [disinfectant] [bleach solution].
- [Ready to use] [pre-diluted] [,] [convenient].
- Reduces the risk of cross-contamination on treated, hard, non-porous surfaces.
- Refill[s] for [Product Name]
- Removes stains
- Removes [Stain(s)/soil(s) from Stains Table]
- Rotate dated product[s] while in inventory.
- Save[s] time and money by not having to mix bleach solution[s]
- See label for specific directions for use.
- Shield from direct sunlight.
- Shelf-stable formula
- Shelf-stable formula for up to two years if unopened.
- SKU
- Suitable for hospital use.
- Suitable for use on hard, non-porous [inanimate] [environmental] [and] [healthcare] surfaces.
- Sold by [:] [Company Name]

- Sporicidal\*, fungicidal, bactericidal and virucidal\*\* disinfectant [bleach] [solution] [is] effective against *Clostridium difficile* spores\* when used per label directions.
- Store [Product Name] [the] [bleach] [solution] in tightly closed containers] [when not in use].
- Store [Product Name] in a cool, dry, and well-ventilated area away from heat and open flame and direct sunlight and inaccessible to children.
- Store at room temperature or cooler for best product performance.
- Suggested areas of usage [on] hard, non-porous [high touch] [objects] [and] [environmental] [and] [healthcare] [surfaces] [in patient care areas] [such as] [Site(s) from Use Sites Table and/or Surface(s) from Surfaces Table]
- Suitable for use on equipment requiring bleach based products
- Spray [Product Name] to kill [Salmonella enterica [Salmonella]] [and] [Staphylococcus aureus [Staph]] on bathroom hard, non-porous surfaces.
- Test solution on small inconspicuous area.
- [Tested] [and] proven to kill SARS-CoV-2 on hard, non-porous surfaces.
- The contact time for a disinfectant is the amount of time a surface must remain wet with the product to achieve disinfection.
- To clean [,] [and] disinfect [and] deodorize in one-step^: Spray surface with bleach solution until completely wet. Allow treated surface to remain visibly wet for 5 five minutes at room temperature. Wipe dry or allow to air dry. Visible soil must be removed prior to disinfecting. [Gloves should be worn].
- This spray bottle is refillable. See refill label for directions for use [and more information].
- Use[d] [to] {inset claim from optional label claims}.
- [Use Site] [Must be] pre-cleaned [prior to] [before] [disinfecting] [disinfection] [of] hard, non-porous [environmental] [and] [healthcare] [surfaces] for [+HIV-1] [+HCV] [+HBV] [and] *Clostridium difficile* spores\*.
- Use[d] to disinfect hard, non-porous surfaces in hospitals, doctor's offices, nursing homes, schools and dental offices.
- [Use to] [cleans] and] disinfect] hard, non-porous surfaces.
- [Use] [Product Name] [can be used] [as a one-step^] cleaner and disinfectant [after removal of fecal contamination] on pre-cleaned hard, non-porous [high touch] [objects] [and] [environmental] [and] [healthcare] [surfaces] [when] [if] [Clostridium difficile spores\*] [are] [likely] [to be present] [of concern].
- [Use] [Product Name] [to effectively clean against odor causing organisms on hard, non-porous [environmental] [and] [healthcare] surfaces when used per label directions.
- [Use on hard, non-porous [environmental] [and] [healthcare] surfaces.]
- [Use] [Product Name] to [successfully] [clean and disinfect] hard, non-porous surfaces.
- [Use] [Product Name] [can be used] [for] [as] [a] disinfectant after removal of fecal contamination on precleaned, hard, non-porous [high touch] [objects] [and] [environmental] [and] [healthcare] [surfaces] [Sites from Use Sites Table].
- [Use] [In the] [area] [center] [station] [department] [s] [listed] [below] [here] [:] [Site(s) from Use Sites Table] [Surface(s) from Surfaces Table].
- [Use Site] [must be] pre-cleaned prior to disinfecting hard, non-porous [environmental] and [healthcare] [surfaces] for [+HIV] [+HBV] [+HCV] and *Clostridium difficile* spores\*.
- Using [Product Name] ensures: {insert claim from list of optional label claims}.
- Virucidal\*\* solution
- Virucide\*\*

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- Virucidal\*\*
- Visible soil must be removed prior to disinfecting.
- Yields 0.65% available chlorine.
- When used per label directions, [Product Name] is an effective way to clean {and/or} deodorize and disinfect [against odor-causing organism] [on] hard, non-porous surfaces listed on this label.
- When used per label directions, [Product Name] is an effective method to clean {and/or} deodorize] [and] disinfect hard, non-porous [environmental] [and] [healthcare] surfaces.
- When used per label directions, [Product Name] is an effective way to clean and deodorize against odor-causing organisms and disinfect hard, non-porous surfaces.
- Wear gloves when using [Product Name].
- Where control of the risks of cross contamination between treated hard, non-porous [environmental] [and] [healthcare] surfaces is of prime importance.

\*Follow the Special Instructions for Cleaning prior to Disinfection [for *Clostridium difficile* spores\*].

+Follow the Special Instructions for Cleaning prior to Disinfection [for bloodborne pathogens].

^A pre-cleaning step is required for efficacy against +HIV, +HBV, +HCV, and *Clostridium difficile* spores\*.

# **{Optional Foreign Language Phrases}**

English: Made In U.S.A.

Spanish: Hecho en los Estados Unidos

English: Use on hard surfaces only

Spanish: Utiliza solamente en superficies duros

The following pictograms are for optional inclusion to the [Product Name] product label.

• Ship and store this end up pictogram (Below)





• Contact Time Clock pictogram







• Microorganism logo



• Made in the USA



# {Sub Label B: For Refill Container}

For refilling [Product Name]

A -4'--- T----- J'---4.

# MICRO-KILL BLEACH GERMICIDAL BLEACH SOLUTION [Product Name]

[Alternate Brand Names: Micro-Kill Bleach Solution, Micro-Kill Bleach Germicidal Solution, Micro-Kill Disinfectant Bleach Solution]

Active Ingredient:	
Sodium hypochlorite	0.65%
Other Ingredients:	99.35%
Total	100.00%

# KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID: If in eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have the product container with you when calling a poison control center or doctor, or going for treatment.

(See [side] [back] panel[s] [on reverse] [of] [outer box] for first aid statement, and additional precautionary statements.)

OR

[(See [side] [back] panel[s] [of] [on] [the] [reverse] [of] [the] [outer box] [label] [for] first aid statement, precautionary statements, and storage and disposal.)]

EPA Reg. No. 37549-2

[DIN: #]

EPA Est. No. xxxxx-xx-xxx Net Contents: [x fl. oz.]

[CAT # xxxx]

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#### **DIRECTIONS FOR USE**

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

## [FOR REFILLING] [TO REFILL] CONTAINERS SOLD SEPARATELY

- 1. Always use personal protective equipment. {AND/OR} Wear gloves when handling this product.
- 2. To refill the spray bottle, remove the trigger sprayer of the container to be refilled.
- 3. Open the refill container of [Product Name].
- 4. Pour the solution from the refill container into the refillable container and [then] replace the trigger sprayer on the refilled container and replace the closure on the refill container.
- 5. Refer to [the label on the] refillable container for **DIRECTIONS FOR USE**.

This product is not to be used as a terminal sterilant/high level disinfectant 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 barriers or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals[.]

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

#### PHYSICAL AND CHEMICAL HAZARDS

This product contains bleach. Do not use this product with other chemicals such as ammonia, toilet bowl cleaners, rust removers, or acid, as this releases hazardous gases.

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

**Pesticide Storage**: Store in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

**Product Disposal**: Products or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

#### **Container Handling And Disposal:**

A. [For Household/Residential Products]

[For rigid nonrefillable container less than 5 gallons]

**Container Handling:** Nonrefillable rigid container. Do not re-use or refill this container. Triple rinse (or equivalent), promptly after emptying. Offer for recycling, if available, or throw in trash.

B. [For Commercial/Industrial/Institutional Products]

[For rigid nonrefillable container less than 5 gallons]

Container Handling: Nonrefillable rigid container. Do not re-use or refill this container. Triple rinse (or equivalent), promptly after emptying. 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.

# C. [For refillable containers]

Container Handling: Refillable containers. Refill this container with [this] [pesticide] [product] [Product Name] only. Do not reuse this container for any other purpose. To clean the container before final disposal: Triple rinse (or equivalent), promptly after emptying. 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.

Medline logo Medline Industries, Inc. Three Lakes Drive Northfield, IL 60093 Medline website Medline barcode

For product emergency, contact: Poison Control Center, 1-800-222-1222

For Technical Information call: 1-800-MEDLINE

For an SDS, call 1-800-MEDLINE and request document [Document ID Number]

# {OPTIONAL ADDITIONAL TEXT FOR USE ON PRODUCT LABEL OR COLLATERAL LABELING}

- Assembled for [and] [distributed by]: [Company Name]
- Available exclusively from: [Company Name]
- Avoid excessive heat.
- Avoid prolonged freezing.
- Avoid direct sunlight.
- Check with your sales representative for updates in your state.
- Complete product line information available by [calling xxx-xxx-xxxx] [contacting xxx-xxx-xxxx]
- Distributed by [:] [Company Name]
- Disposable [solution]
- Each [bottle] [container] of [Product Name] contains [x fl. oz.] [x gallon[s]] [of] [RTU] 0.65% bleach solution.
- Each [1] [one] [case] contains [X] [x gallon bottles] [of] [RTU] 0.65% bleach solution.
- [Expiration date] [EXP] [EXP DATE] [XXXXXX]
- For complete product line information, call [Company Name]
- For refilling [Product Name]
- For product questions, call [name and phone number]
- Fresh bleach scent
- [Lot Number] [Lot xxxxxx]
- Made in [the] U.S.A.
- Manufactured for [:] [Company Name]
- Manufactured [and] [Distributed] [Sold] in the U.S.A.

- [No mixing] [No measuring] necessary.
- Not for sale or use after [date].
- [Packaged] [Packed] for [XXXXXXX]
- [Pre-mixed] [pre-diluted] [ready-to-use] 0.65% [bleach solution].
- [Product Name] Contains 0.65 % available chlorine.
- [Product Name] Contains 0.65% bleach
- [Product Name] [Contains] [0.65% [active] bleach.
- [Product Name] is for refilling [refillable] containers.
- [Product name] has a 2 year shelf life if unopened.
- [Product name] is shelf stable [for up to 2 years if unopened].
- [Product Name] contains 0.65% bleach
- [Product Name] [is a solution that] contains 0.65% bleach
- Protect from freezing
- [Ready to Use] [RTU]
- [Ready to use] [pre-diluted] [,] [convenient].
- Refill[s] for [Product Name]
- Rotate dated product[s] while in inventory.
- Shield from direct sunlight
- Shelf-stable formula
- Shelf-stable formula for up to two years if unopened
- Sold by [:] [Company Name]
- Store at room temperature or cooler for best product performance.
- Store [Product Name] [the] [bleach] [solution] in tightly closed containers] [when not in use].

{Optional Foreign Language Phrases}

English: Made In U.S.A.

Spanish: Hecho en los Estados Unidos

The following pictograms are for optional inclusion to the [Product Name] product label.

• Ship and store this end up pictogram (Below)



• Made in the USA



• Contact Time Clock pictogram







• Microorganism logo

