



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 16, 2019

Abigail T. D. Wacek
Technology Sciences Group
Agent for Medline Industries, Inc.
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Subject: PRIA Label Amendment – Adding efficacy claims, emerging pathogen guidance, marketing statements and alternate brand names.
Product Name: MICRO-KILL BLEACH GERMICIDAL BLEACH WIPES
EPA Registration Number: 37549-1
Application Date: September 20, 2018
Decision Number: 550998

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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the [August 19, 2016, Guidance To Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels \(“Guidance”\), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

- i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
- b. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OIE, the pathogen's viral subgroup is [small non-enveloped, large non-enveloped, enveloped].
 - c. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term B.3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term B.3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term B.3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.
 5. Terms B.1 through B.4 above shall become immediately void and ineffective if registration for use against label viruses is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

The following Alternate Brand Names are acceptable and have been made part of the file for this product:

- a. MICRO-KILL BLEACH GERMICIDAL WIPES
- b. MICRO-KILL DISINFECTANT BLEACH WIPES

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. 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 the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. 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) list 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. 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 Compliance.

In addition, the Storage Stability and Corrosion Characteristics data submitted as part of this application was found acceptable.

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 Ben Chambliss by phone at (703) 308-8174, or via email at chambliss.ben@epa.gov.

Sincerely,



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

Enclosure

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{Sub Label A: Ready to Use Wipes}

MICRO-KILL BLEACH GERMICIDAL BLEACH WIPES [Product Name]

[Alternate Brand Name: Micro-Kill Bleach Wipes, Micro-Kill Bleach Germicidal Bleach Wipes & Bucket, Micro-Kill Bleach Wipes & Bucket, Micro-Kill Bleach Germicidal Wipes, Micro-Kill Disinfectant Bleach Wipes]

These wipes [are] antimicrobial, sporicidal*, 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%

~Other ingredients do not include the weight of towelette.

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* and *Candida auris****, precautionary statements, and storage and disposal.)]

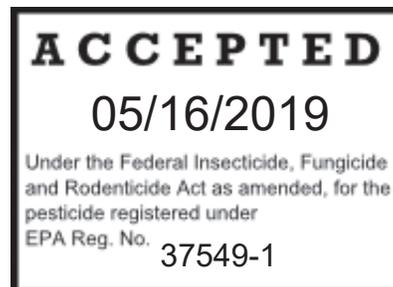
EPA Reg. No. 37549-1

EPA Est. No. xxxxx-xx-xxx

[DIN: #]

U.S. Patent No. xxxxx

Net Contents [xx.xx] oz.



Micro-Kill Bleach Germicidal Bleach Wipes, 37549-1

Medline Industries

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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.

[HOSPITAL] [HEALTHCARE FACILITY] [GENERAL] DISINFECTION

1. Always use personal protective equipment.+
2. Open [Product Name] [packet] [canister].
3. Remove premoistened [X” x X”] towelette.
4. Apply [premoistened] towelette and wipe desired surface to be disinfected.
5. Gross soil must be removed prior to disinfecting. {*Note: 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*], a 2 minute contact time is required [for efficacy against] [to kill] *Candida auris****, and a 3 minutes contact time is required [for efficacy against] [to kill] *Clostridium difficile* spores*. [Reapply] [Use] [as many] [additional] [towelettes] as necessary to ensure that the surface remains visibly wet for the entire contact time.

OR

Allow treated surfaces to remain visibly wet for 3 minutes. [Reapply] [Use] [as many] [additional] [towelettes] as necessary to ensure that the surface remains visibly wet for the entire contact time.

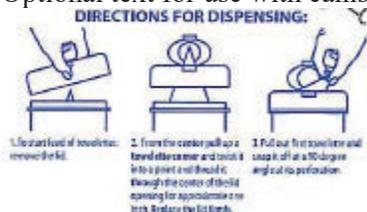
6. Allow surface to air dry and discard [used] towelette[s] and [empty] [packet] [canister] [see **STORAGE AND DISPOSAL**].

{Optional text for use with canister offerings}

[TO OPEN CANISTER:

1. Always use personal protective equipment.+
2. Remove lid from canister.
3. [Remove [foil] [seal]] [from mouth of canister] [if present] [and discard].
4. Lift flap [in] [on] canister lid.
5. Pull up corner of center towelette [and] [,] snap off [,] and discard. Take the next towelette, [twist to a point] [and thread] [before] [prior to] [then] [thread] [threading] through dispenser hole in lid.
6. DO NOT PUSH FINGER THROUGH OPENING
7. Replace lid. Pull out exposed towelette [to perforation] and snap off [at a 90° angle]. The next towelette pops up automatically.
8. Snap center flap down when finished to retain moisture.
9. Do not flush towelette [into] [down the] toilet.]

{Optional text for use with canister offerings}



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{Optional text for single use packet}

[TO OPEN PACKET: Always use personal protective equipment.+ Tear open [along dotted line] [at tear notch] [along the top edge of pouch]. [Pull out] [Remove] towelette. [Unfold towelette before use.] Dispose used towelette in trash. Do not flush towelette into toilet. Discard used towelette in designated infectious waste container for disposal according to Federal, State and Local regulations. Offer empty packet for recycling if available or discard in trash.

**[FOR FILLING] [TO FILL] [TO FILL OR REFILL] CONTAINERS [SOLD SEPARATELY]
{OR}**

[FOR REFILLING] [TO REFILL] [FOR FILLING OR REFILLING] CONTAINERS [SOLD SEPARATELY]

1. Always use personal protective equipment. {AND/OR} Wear gloves when handling this product.
2. To [re]fill the canister with towelettes cut open sealed pouch and place the roll of towelettes into the canister.

OR

To fill or refill the bucket with towels, place the sealed pouch containing the roll of towels in the bucket and then cut open the pouch.

OR

To fill or refill the bucket with towels, cut open the sealed pouch containing the roll of towels and then place the open pouch in the bucket.

3. Pull up corner of center towelette [and] [,] snap off [,] and discard. Take the next towelette [and] [,] [twist to a point] [and thread] [before] [prior to] [then] [thread] [threading] through dispenser hole in lid.
4. DO NOT PUSH FINGER THROUGH OPENING
5. Replace lid. Pull out exposed towelette [to perforation] and snap off [at a 90° angle]. The next towelette pops up automatically.
6. Snap center flap down when finished to retain moisture.
7. Do not flush towelette [into] [down the] [toilet.]
8. Refer to [label on the] canister for **DIRECTIONS FOR USE**.

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

+KILLS HIV-1, HBV, AND HCV ON PRECLEANED 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 associated with the potential for transmission of HIV-1 (associated with AIDS), HBV, and HCV.

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

- **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] [Product Name].

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- **CONTACT TIME:** Allow surface(s) to remain visibly 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*], a 2 minute contact time is required [for efficacy against] [to kill] *Candida auris****, and a 3 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 application [of] [with] [a clean] [cloth] [,] [mop] [,] [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.
- **INFECTIOUS MATERIAL 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.

*****SPECIAL [LABEL] INSTRUCTIONS FOR CLEANING PRIOR TO DISINFECTION AGAINST *Candida auris*:**

- **PERSONAL PROTECTION:** Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering.
- **CLEANING PROCEDURE:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the product. Pre-cleaning is to include vigorous wiping and/or scrubbing and all visible soil is removed. 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 the organism. Restrooms are to be cleaned last. Do not reuse soiled cloths.
- **INFECTIOUS WASTE 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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†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 and 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: *[For product sold in canisters]* Keep [Product name] in a tightly closed canister when not in use. Store [canister] [Product name] in [a] cool, dry, and well-ventilated area away from heat, open flame, direct sunlight and inaccessible to children.

[For product sold in individual packets] Store in a cool, dry, and well-ventilated area away from heat, open flame, direct sunlight and inaccessible to children.

Pesticide Disposal: [Wastes resulting from the use of [Product name] must be disposed of [on site] [in the trash] [or] [at an approved waste disposal facility]. [Dispose of [used] towelettes in the trash] [after use]. [Do not flush towelette [into] [down the] toilet.]

Container Handling and Disposal:

A. *[For Household/Residential Products]*

[For rigid nonrefillable canister less than 5 gallons]

Container Handling: Nonrefillable rigid canister. Do not re-use or refill this canister. [Triple rinse (or equivalent), promptly after emptying.] [Offer for recycling, if available][Recycle empty canister], or [throw] [discard] in trash] [.]

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

[For rigid nonrefillable canister less than 5 gallons]

Container Handling: Nonrefillable rigid canister. Do not re-use or refill this canister. [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.] [Recycle empty canister or discard in trash.]

C. *[For Refillable Canisters]*

Container Handling: Refillable canister. Refill this canister with [this] [pesticide] [product] [product name] only. Do not reuse this canister for any other purpose. To clean the canister 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.

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D. [For individual packed towelettes]

Container Handling: Towelettes: Dispose of [towelette] in trash after use. [[Do not flush] [.]
[towelette] [into] [down the] toilet.]. Offer empty packet for recycling if available or discard in trash.

E. [For nonrefillable pouch]

Container Handling: Nonrefillable pouch. Do not re-use or refill this pouch. Completely empty contents of pouch into canister, then offer [empty pouch] for recycling if available or discard in trash.

[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]

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[Efficacy Claims]

***SPORICIDAL / SPORES** 3 minute[s] contact time

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

****VIRUCIDAL / VIRUSES** 30 second[s] contact time

[SMALL NON-ENVELOPED 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 ([Novel] H1N1) [CDC 2009712192]
- Influenza A Virus (Hong Kong) [ATCC VR-544]
- Influenza B Virus (Strain B/Hong Kong/5/72) [ATCC VR-823]
- Respiratory Syncytial Virus [(RSV)] [ATCC VR-26]

[ENVELOPED VIRUSES] [BLOODBORNE PATHOGENS]

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

[ANIMAL VIRUSES]

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

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BACTERICIDAL / BACTERIA 30 second 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)] [*Escherichia coli*] [(*E. coli*)] [CDC 1001728]
- *Klebsiella pneumoniae* [(*K. pneumoniae*)] [ATCC 4352]
- *Klebsiella pneumoniae*-CRKP [(*K. pneumoniae*)] [(Carbapenem resistant *Enterobacteriaceae*)] [(*K. pneumoniae*)] [(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 pneumoniae*-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* [(*S. aureus*-LRSA)] [NRS 119]
- *Listeria monocytogenes* [(*L. monocytogenes*)] [(*Listeria*)] [ATCC 19117]
- Methicillin Resistant *Staphylococcus aureus* [(*S. 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]

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- *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]

*****FUNGICIDAL / FUNGUS 2 minute contact time**

- *Candida auris* [(*C. auris*)] [(CDC AR-0381)]

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For use on hard, non-porous, nonfood contact surfaces in the following Use Sites:		
<i>{Note to reviewer: These sites to be used where indicated in claims.}</i>		
<ul style="list-style-type: none"> - Airplanes - Aviation - Bathroom[s] - Cafeterias - Clean rooms - Clinical laboratory[ies] [lab[s] - Churches - Colleges - Cruise ships - Day Care Centers - Dental laboratory[ies] [lab[s] - Dental offices - Doctor’s offices - Dormitories - Emergency medical sites - Emergency rooms - EMS sites - Extended care facilities - Farm premises - Fire stations - General nursing stations - General stores - Gymnasiums - Health clubs 	<ul style="list-style-type: none"> - Home healthcare sites - Hospital laboratory[ies] [lab[s] - Hospitals - Hotels - Houses - ICU/CCU - ISO9000 environments - Janitorial surfaces - Kitchen[s] - Laboratories - Laundromats - Laundry rooms - Locker rooms - Medical laboratory[ies] [lab[s] - Mortuaries - Motels - Nursery schools - Nursing stations - Nursing homes - Nursing homes - Nursing stations - Offices - Out patient care clinics - Pediatric offices 	<ul style="list-style-type: none"> - Physical therapy offices - Physician offices - Police stations - Poultry houses - Radiology rooms - Recovery room - Recreation centers - Rehabilitation facilities - Renal dialysis rooms - Rest rooms - Restaurants - Schools - School buses - Shelters - Shower rooms - Skilled long term care facility[ies] - Skilled nursing facility [SNF] - Supermarkets (non-food contact surfaces) - Surgeries - Universities - Veterinarian clinics

For use on hard, non-porous, nonfood contact of the following Surfaces:		
<i>{Note to reviewer: These surfaces to be used where indicated in claims.}</i>		
<ul style="list-style-type: none"> - [Blood] glucose meters† - Appliances - Ambulance equipment - Bar code readers - Bathtubs - Bathroom handrails - Bathroom fixtures - Bed pan[s] - Bed rails - Bedside commodes - Bedside tables - Bedside testing equipment 	<ul style="list-style-type: none"> - Faucets - Floors - Flush handles - Formica - Freezers (exterior surfaces) - Garbage cans - Glass - Glazed [ceramic] tiles - Glazed tile walls - Glazed porcelain - Glucometers† - Hand railings 	<ul style="list-style-type: none"> - Plastic mattress covers - Plastics - Playpens - Plexiglas - Point-of-care equipment - Room temperature control knobs - Showers - Shower head control knobs - Shower fixtures - Shower stall(s) - Sinks

Micro-Kill Bleach Germicidal Bleach Wipes, 37549-1

Medline Industries

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For use on hard, non-porous, nonfood contact of the following Surfaces:		
<i>{Note to reviewer: These surfaces to be used where indicated in claims.}</i>		
– Biological safety [cabinets]	– Hard plastic surfaces	– Sink tops
– [hood]	– Headsets	– Sphygmomanometers
– Cabinet handles	– High touch surfaces	– Stainless steel
– Carts	contaminated with fecal	– Stall doors
– Cell phones	matter	– Stretchers
– Cellular phones	– Highchairs	– Support bars
– Chair[s]	– Infusion pumps	– Tables (non-food contact)
– Closet handles	– Instrument stands	– Table tops (non-food
– Computer keyboards	– IV pole	contact)
– Computer monitors	– Laboratory counters	– Telemetry equipment
– Computer screens	– Laminated [plastic]	– Telephones
– Countertops	countertops	– Toilet bedpan
– Dental counters	– Lamps	– Toilet exteriors
– Diagnostic equipment	– Light switches	– Toilet rims
– Dialysis machines	– Linoleum	– Toilet seats
– Diaper pails	– Medical counters	– Tub and shower fixtures
– Digital phones	– Mobile phones	– Tub and shower walls
– Digital screens	– Multi-module monitor	– Trash cans
– Door knobs	[controls] [touch screens]	– Tray table
– Door levers	[cables]	– Vanities
– Drain boards	– Patient bed controls	– Vanity tops
– Drawer pull[s]	– Patient care equipment	– Ventilator control panel
– Electronic digital equipment	– Patient monitoring	– Vinyl
– Equipment [and monitors]	equipment	– Water control knobs
– Exam tables	– PVC tubing (exterior	– Wheel chairs
– External toilet/urinal	surfaces)	– Wireless phones
surfaces	– Pharmaceutical exhaust	
– External	hoods	
microwave/oven/stove/	– Phone and call button	
stove-tops/refrigerator	– Phone cradle(s)	
surfaces		

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

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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 pathogen that is a/an...	...follow the directions for use for the following organisms on the 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 [hard, porous/non-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 [hard, porous/non-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 3 minute contact time is required for use against *Clostridium difficile* spores*.
- A 2 minute contact time is required for use against *Candida auris****.
- A 1 minute contact time is required for use against *Candida albicans* and *Trichophyton interdigitale*.
- A 30 second contact time is required for *virucidal** and bactericidal* uses.
- A potable water rinse is required for food contact surfaces.
- Active ingredient is bleach diluted to 0.65%.
- Aids in reducing cross contamination between treated surfaces.
- All of the [raw materials] [components] of [Product Name] including the canister[s] 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 [wipes]
- Antimicrobial [wipes]

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- 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 wipes
- Bathroom [disinfectant] wipes for use on hard, non-porous [environmental] surfaces.
- Bleach [disinfectant] [germicidal] wipe[s].
- Bleach-based formula means no quat-binding concerns with [Product Name].
- Bleach disinfectant wipes [are] saturated with 0.65% bleach solution [are] [,] [RTU] for hospital use.
- Broad spectrum disinfectant [wipes].

- 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 on glucometers[†].
- [Can be used] [For use] to disinfect hard, non-porous surfaces of glucometers[†], [and] [stethoscopes] [and] [sphygmomanometers] [in glucometer[†] rental programs].
- Catalog number
- 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] [Used to] disinfect [**Surface(s) from Surfaces Table**]
- Carbapenem Resistant *Klebsiella pneumoniae* (CRKP) is a member of the family *Enterobacteriaceae* [(JCRE)].
- Carbapenem Resistant *Klebsiella pneumoniae* [(CRKP)][or] [-] [(CRE)]
- Cleans, disinfects, and deodorizes.
- Company Name [Lot Number] [Lot xxxxxx]
- Contact Time: 3 minutes for *Clostridium difficile* spores*.
- Contact Time: 2 minutes for *Candida auris****.
- Contact Time: 1 minute for *Candida albicans* and *Trichophyton interdigitale*.
- Contact Time: 30 seconds for *virucidal*** and *bactericidal* uses.
- Contains solution of 0.65% [available chlorine] [active] [bleach].
- [Can be used on] [For use on] Glucometers[†].
- *Clostridium difficile* spores*
- Convenient, Pre-Saturated Disposable towelette.
- Convenient, Disposable Pre-Saturated towelette.
- Cost Savings[:]

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- Daily use [this] product with [sporicidal*] [bactericidal] [virucidal**] [and] [fungicidal***] [activity] [properties] [killing properties]
- Deodorizes by killing the germs that cause odors.
- Designed for use by Environmental Services Professionals.
- Destroys [the following allergens] [:] [dust mite particles] [,] [cockroach particles] [and] [pet dander] [allergens] [found in dust].
- Disposable, [germicidal], [antimicrobial], [sporicidal*], [virucidal**], [bactericidal], [fungicidal***] wipes.
- Disinfects, cleans, deodorizes
- Disinfectant
- Disinfects
- Disinfecting
- Disinfectant wipe
- Disinfects and deodorizes by killing germs and their odors.
- [Disinfectant] [Disinfecting] [bleach] wipe[s].
- Disinfects hard, non-porous healthcare surfaces [including/such as [**Surface(s) from Surfaces Table**]].
- Distributed by [:] [company name]
- Disposable [wipes]
- Do not use on glassware, utensils or dishes.
- Do not use [Product name] [as a diaper wipe] [or] [for personal cleansing] [as a skin wipe] [sanitizer] [sanitizing] [or] [disinfectant] [disinfecting] wipe.
- Durable [, low lint] [,] [100%] polyester cloth [is designed [for] [to] use on sensitive equipment] [to save time and money by not having to mix bleach solutions].
- Each [1] [one] [case contains [X] [dispenser] boxes of [X] [packets] [of] [individually [wrapped] [packaged] [sealed] towelette(s)].
- Each [1] [one] case contains [x] canisters [of] [X] [count] [x” x x” towelette].
- [Easy] [,] [Product Name] [Can be used] [as a] [is a] one-step^ cleaner and disinfectant bleach wipe.
- Easy and convenient to use.
- Effective disinfection at your convenience when used per label directions.
- Effective disinfection of hard-to-kill microorganisms listed on the label on hard, non-porous surfaces when used per label directions.
- Effective against [bacteria] [germs] [viruses] [fungi] [spores] when used per label directions.
- [Eliminates] [or] reduces odors caused by germs.
- Ensure that surface remains visibly wet for the entire contact time.
- EPA registered to kill *Clostridium difficile* spores* in 3 minutes.
- 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.

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- Formulated [for] [cleaning and disinfecting] [in [just] one step^.
- [For disinfection of] [For disinfecting] [Disinfects] [Glucometers†] [,] [and] [patient care equipment] [,] [and][point-of-care equipment] [and] hard, non-porous healthcare surfaces.
- For complete product line information, call [company name].
- For best product performance store at room temperature or cooler.
- For cleaning and disinfecting [when] [if] *Clostridium difficile* spores* [are] [likely] [to be present] [of concern].
- 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 removal of fecal contamination] on precleaned, hard, non-porous [high touch] [objects] [and] [environmental] [and] [healthcare] [surfaces]
- For use on bathroom surfaces.
- For daily use in discharge cleaning in healthcare facilities.
- For use on hard, non-porous [environmental] [and] [healthcare] surfaces.
- 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 in required. Do not use on glassware, utensils, or dishes.
- For use on hard, non-porous surfaces that require the use of bleach for disinfecting, cleaning and maintenance.
- For use [in] [on] [the] [Sites from Use Sites Table] [Surfaces from Surfaces Table].
- For use in the [area] [center] [station] [department][s] [listed] [below] [here] [:] [Site(s) from Use Sites table] [Surface(s) from Surfaces Table]
- Fresh bleach scent
- Fungicidal wipes***
- Fungicidal***
- Fungicide***
- Germicidal wipes [Toallitas Germicidas]
- Germicidal [disposable] wipes.
- Germicidal
- Germicide
- Gloves must be worn.
- Gross soil must be removed prior to disinfecting.
- Help[s] reduce the spread of germs on treated, hard, non-porous surfaces.
- Helps reduce risks of cross-contamination 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.

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- Kills Influenza A Virus, commonly known 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 3 minutes.
- Kills odor-causing [bacteria] [germs]
- Kills [*Candida auris****] [*C. auris****] on hard, non-porous surfaces in 2 minute contact time.
- Kills up to 99.999% or five logs of [*Candida auris****] [*C. auris****] on hard, non-porous surfaces.
- *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 disinfection recommendation for OSHA blood borne pathogen standard.
- Meets efficacy standards for hospital disinfection.
- Moist inanimate surface wipes.
- Moist [bleach] wipes for hard, non-porous [healthcare] [,] [and] [environmental] [inanimate] surfaces.

- [No mixing] [No measuring] necessary
- Not a skin wipe. (pictogram)
- Not a baby wipe. (pictogram)
- 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] [disinfectant [and] cleaner] [cleaning [and] disinfecting] [bleach] [wipe[s]] that [is] [are] [sporicidal*], [virucidal**], [bactericidal] [and] [fungicidal***].
- One-step^ [cleaner [and] disinfectant] [disinfectant [and] cleaner] [cleaning and disinfecting] [bleach] wipe[s].
- One-step^ [antimicrobial], [sporicidal*], [virucidal**], [bactericidal], [fungicidal***], disinfectant wipe[s].
- [One-step^] [cleaner and disinfectant] bleach wipe[s].

- [Packaged] [Packed] for [XXXXXXXX]
- Penetrates and breaks down [dust mite particles] [,] [cockroach particles] [and] [pet dander] [allergens] [found in dust].

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- Preclean prior to disinfecting hard, non-porous surfaces for [+HCV] [,] [+HIV-1] [and] [+HBV] [and] [,] [*Clostridium difficile* spores*] [and] [*Candida auris****].
- Premoistened [3” x 3”] [3” x 4”] [5” x 9”] [6” x 6”] [6” x 7”] [6” x 8”] [6” x 9”] [7” x 8”] [7” x 9”] [“8 x 7”] [8” x 9”] [8” x 10”] [9” x 6”] [9” x 9”] [12” x 12”] [14” x 14”] [9” x 12”] [12” x 9”] [X” x X”] Towelette
- [Product Name] [kills] [has demonstrated effectiveness against] [Influenza A Viruses including [Pandemic 2009 H1N1(formerly called Swine Flu)] [and] [Influenza Virus (Hong Kong strain)]] when used per label directions.
- [Product Name] [is] [are] [a] [one-step^ cleaner and disinfectant] [bleach] [wipe[s]].
- [Product Name] kills [*Clostridium difficile* spores*] [**VIRUSES****, **BACTERIA and FUNGI FROM LISTS**].
- [Product Name] is tested according to AOAC efficacy testing methods for hospital disinfection.
- [Product Name] [is] [a] [are] [for use on hard non-porous [environmental] surfaces in] [**Surface(s) from Surfaces Table**] [**Site(s) from Use Sites Table**]
- [Product Name] [is a] [are] premoistened disposable towels 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] disinfects glucometers†, patient care equipment, point-of-care equipment and hard, non-porous healthcare surfaces such as [Surface from Surfaces Table].
- [Product name] kills Avian Influenza A Virus[es] [(H3N2)], [(H5N1)] and [(H7N9)] on hard, non-porous surfaces in [poultry house[s] [and] [farm premises]].
- [Product Name] [is EPA registered [and] [has a] [with a] *Clostridium difficile* spore* kill claim with [a] 3 minute contact time [.] [and] [has been registered by the Federal EPA] [.] [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] [is EPA registered] [and] [has] [with] [a] [kill] [efficacy] claim[s] for [**VIRUS FROM LIST**] [kill] [efficacy] claim[s] with a 30 second contact time[.] [and] [has been registered by the Federal EPA]. [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] [is EPA registered] [and] [has] [with] [a] [kill] [efficacy] claim[s] for [**BACTERIA FROM LIST**] [kill] [efficacy] claim[s] with a 30 second contact time[.] [and] [has been registered by the Federal EPA]. [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] [is EPA registered] [and] [has] [with] [a] kill [efficacy] claim[s] [for] [**FUNGUS FROM LIST**] [kill] [efficacy] claim[s] with a 1 minute contact time[.] [and] [has been registered by the Federal EPA]. [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] [bleach] [wipes] [were] [was] specifically [designed] [created] to disinfect [Glucometers†] and [point of care] [bedside] [testing] [equipment] [and] [patient care equipment] [to meet] [to comply with] [the equipment manufacturers maintenance [requirements] [protocols] [procedures]].

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- [Product Name] [bleach] [wipes] [can be used by [Paramedics] [,] [Policemen] [,] [Firemen] [and] Veterinarians] to disinfect hard, non-porous [environmental] [and] [healthcare] surfaces.].
- [Product Name][and][is][are][EPA Registered][antimicrobial product[s]][disinfectant[s]][with label claims for Avian{(Bird)} Flu].
- [Product Name] [is] [a] [are] germicidal [bleach] wipe[s].
- [Product Name] [is] [a] [are] [stabilized] [bleach] wipe[s].
- [Product Name] [is] [an] [are] [Antimicrobial] [bleach] wipe[s].
- [Product Name] [is] [a] [are] [sporicidal*] [bleach] wipe[s].
- [Product Name] [is] [a] [are] [virucidal**] [bleach] wipe[s].
- [Product Name] [is] [an] [are] [Antibacterial] [bleach] wipe[s].
- [Product Name] [is] [a] [are] [Bactericidal] [bleach] wipe[s].
- [Product Name] [is] [a] [are] [fungicidal***] [bleach] wipe[s].
- [Product Name] [is] [a] [are] [surface] [wipe[s]] [that] [is] [are] [highly absorbent] [and] [tear-resistant].
- [Product Name] [is] [a] [are] [Bleach] [disinfectant] [disinfecting] wipe[s].
- [Product Name] [is] [a] [an] [are] [Ready to Use] [EPA registered] [hospital disinfectant] [sporidical*, virucidal**, bactericidal, fungicidal***], [antimicrobial] [bleach] wipes.
- [Product Name] [wipe[s]] [is] [a] [are] [for] [Can be used] [for] [cleaning] [,] [and] [deodorizing] [and] [disinfecting] [**Surfaces from Surfaces Table**].
- [Product Name] [is] [a] [are] [cleaner disinfectant] [is] [that] [kills] [Blood borne pathogen[s] [(BBP)]] [BBP] [+HIV-1, +HBV and +HCV] when used per label directions [.]
- [Product Name] [can be used for cleaning and disinfecting] [that kills] [blood borne pathogens [(BBP)]] [BBP] [+HIV-1, +HBV and +HCV] on hard non-porous surfaces when used per label directions.
- [Product Name] [is] [a] [are] [one-step] [cleaner disinfectant[s]].
- [Product Name] [can be used to] [clean[s] and disinfect[s]] [hard, non-porous] medical equipment surfaces.
- [Product Name] contains [towels saturated with] Medline[’s] 0.65% [bleach] solution.
- [Product Name] cleans, deodorizes and disinfects.
- [Product Name] kills *Clostridium difficile* spores* in 3 minutes.
- [Product name] [is] [are] not for [use on] [cleansing] [or] [sanitizing] [or] [disinfecting] skin.
- [Product name] contains bleach.
- [Product name] [satisfies] [satisfied] EPA guidelines [for killing] [for efficacy claims for] [see list of microorganisms on product label].
- [Product Name] [is] [are] [a] one-step^ [cleaning] [cleaner] and [disinfecting] [disinfectant] wipe[s].
- [Product Name] is used [as] [for] [to]
- [Product Name] is an EPA registered sporidical* bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is an EPA registered bactericidal bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is an EPA registered fungicidal*** bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is an EPA registered virucidal** bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is an EPA registered antimicrobial bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] helps controls the spread of germs on most treated hard, non-porous surfaces.
- [Product Name] can be used on glucometers[†].

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- [Product Name] [is a] [one-step^] [multipurpose, broad spectrum] [bleach] disinfectant [wipe] that kills pathogens within 3 minutes.
- [Product Name] [is a] [one-step cleaner disinfectant^] [that [cleans and disinfects] hard, non-porous surfaces in just one step.^
- [Product Name] [can be used] as a one-step^ disinfectant on [precleaned] hard, non-porous surfaces for disinfecting against blood borne pathogens.
- [Product Name] is a [Unit dose] [single use] [individual] bleach saturated [wipe].
- [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] [is] [are] sporicidal*, 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 Suggested Areas of Usage] [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] is saturated with a solution of bleach diluted to 0.65%
- [Product Name] are one-step^ cleaner and disinfectant wipes.
- [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] can be used [as a bleach wipe] to clean, deodorize, and disinfect and kills [up to 99.9999% of] [tough to kill] *Clostridium difficile* spores* in 3 minutes [in the presence of organic soil] after pre-cleaning on hard, non-porous environmental and healthcare surfaces.
- [Product Name] is an EPA registered and [easy to use] [Ready to Use] [as] sporidical* bleach wipe cleaner, deodorizer, and disinfectant and kills [up to 99.9999% of] [tough to kill] *Clostridium difficile* spores* [in 3 minutes [in the presence of organic soil] [after pre-cleaning] on hard, non-porous environmental and healthcare surfaces.
- [Product Name] can be used [as a bleach wipe] 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 EPA registered and [easy to use] [Ready to Use] [as a] virucidal** and bactericidal bleach wipe cleaner, deodorizer, and disinfectant and [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 wipe 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 EPA registered and [easy to use] [Ready to Use] [as a] fungicidal*** bleach wipe cleaner, deodorizer, and disinfectant and [kills] **FUNGI FROM LIST** in 1 minute [in the presence of organic soil] on hard, non-porous environmental and healthcare surfaces.
- Protect from freezing
- Presaturated towel

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- Proper concentration of bleach delivered [every time] for surface disinfection and maximum coverage. Reapply as necessary to ensure surface remains visibly wet for entire contact time.
- [Ready to use] [RTU]
- Ready to Use [hospital disinfectant].
- Ready to use [EPA registered] [pre-saturated] [hospital disinfectant] [bleach wipe[s]].
- Ready to use one-step^ cleaner/disinfectant for use on hard, non-porous surfaces where disinfection is required.
- Reduces [dust mite particles] [,] [cockroach particles] [and] [pet dander] [allergens] [found in dust].
- Refill[s] for [Product Name]
- Removes stains
- Removes [**Stain(s)/soil(s) from Stains Table**]
- Rotate dated product[s] while in inventory.
- Reduces the risk of cross-contamination on treated, hard, non-porous surfaces.
- See label for specific directions for use.
- Shield from direct sunlight
- Shelf-stable formula
- Shelf-stable formula for up to two years if unopened.
- Saturated with a solution that contains 0.65% [of active] bleach.
- Single Use Only
- SKU
- Suitable for hospital use
- Suitable for use on hard, non-porous [inanimate] [environmental] [and] [healthcare] surfaces.
- Sold by [:] [Company Name]
- Sporicidal*
- Sporicide*
- Sporicidal* wipes
- [Sporicidal*] [Bactericidal] [Fungicidal***] [Virucidal**]
- Sporicidal*, fungicidal***, bactericidal and virucidal** disinfectant [bleach] [wipes] [are] effective against *Clostridium difficile* spores* when used per label directions.
- Store at room temperature or cooler for best product performance.
- Store [Product Name] in sealed packets] [when not in use].
- Store [Product Name] in tightly closed canister] [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.
- 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**] [**Surface(s) from Surface(s) Table**].
- Suitable for use on equipment requiring bleach based products.
- Test wipe on small inconspicuous area.
- The easy, convenient way to clean and disinfect with [Product Name].

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- The contact time for a disinfectant is the amount of time a surface must remain visibly wet with the product to achieve disinfection.
- There are [X] [packets] [of] [individually [wrapped] [packaged] [sealed]] towelette(s) [in a [dispenser] box]. [Each] [1] [A] [dispenser] [box contains X [packets] [of] [individually] [wrapped] [packaged] [sealed]] towelette(s).
- There are [X] [dispenser] boxes [of X individual packets per [dispenser]box] [in a] [per] [case] [carton] [shipping carton].
- [This] durable, low-lint [100%] polyester cloth is designed to save time and money by not having to mix bleach solutions.
- [To clean [,] [and] disinfect [and] deodorize in one-step^: Wipe surface with towel and keep surface visibly wet for 3 minutes at room temperature. Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting. Gloves should be worn. A pre-cleaning step is required for *Clostridium difficile* spores* and *Candida auris**** disinfection.
- This container is refillable. See refill label for directions for use [and more information].
- [These wipes are sporicidal*, virucidal**, bactericidal, and fungicidal*** and can be used to clean, deodorize and disinfect hard, non-porous healthcare and environmental surfaces, patient care equipment and point-of-care equipment [in one-step^]].
- Unit dose
- Use[d] [to] {inset claim from optional label claims}.
- Use in public or common places where you are concerned about germs on hard, non-porous surfaces.
- Use wipes to kill [*Salmonella enterica* [Salmonella]] [and] [*Staphylococcus aureus* [Staph]] on bathroom hard, non-porous surfaces.
- Use[d] to disinfect hard, non-porous surfaces in hospitals, doctor’s offices, nursing homes, schools and dental offices.
- [Use to] clean and disinfect hard, non-porous surfaces when used per label directions.
- [Use] [Product Name] [as] [is] [a] [can be used] [as a] one-step^ cleaner and disinfectant.
- [Use] [Product Name] [can be used] after removal of fecal contamination on precleaned, hard, non-porous [high touch] [objects] [and] [environmental] [and] [healthcare] [surfaces] [when] [if] *Clostridium difficile* spores* [are] [likely] [to be present] [of concern].
- [Use] [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] [**Site(s) from Use Sites Table**] [**Surface(s) from Surfaces Table**]
- Using [Product Name] ensures: {insert claims from optional label claims}.
- Virucidal** wipes
- Virucide**
- Virucidal**
- Yields 0.65% available chlorine.
- Wear gloves when using [Product name].
- When used per label directions, [Product Name] is an effective way to [clean] [,] [and] [deodorize] [and] [disinfect] [against odor-causing organism] [on] hard, non-porous surfaces listed on this label.

Micro-Kill Bleach Germicidal Bleach Wipes, 37549-1

Medline Industries

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- When used per label directions, [Product Name] is an effective method to [clean] [and] [,] [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.
- Where control of the risks of cross contamination between treated hard, non-porous [environmental] [and] [healthcare] surfaces is of prime importance.
- Wipes

*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, *Candida auris****, and *Clostridium difficile* spores*.

{Optional Foreign Language Phrases}

English: Made In U.S.A.

Spanish: [Hecho en los Estados Unidos]

English: Use on hard, non-porous surfaces only. Not a skin wipe. Not a baby wipe.

Spanish: Utilizar solo en superficies duros non-porous. No es paño limpiador para la piel. No es toallita de bebé.

English: Use on hard, non-porous surfaces only

Spanish: Utiliza solamente non-porous en superficies duros.

English: Not for use on skin

Spanish: No para uso sobre la piel

French: A ne pas utiliser sur la peau

English: Not a skin wipe

Spanish: Noes una toalla para la piel

English: Not a baby wipe or adult wipe

Spanish: No una toalla para los bebé’s o toalla para adultos

English: It is prohibited to use as a wipe for babies or adults

Spanish: Es prohibido a utilizar como una toalla para los bebé’s o adultos

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

- Barcode
- DOT graphic
- Universal Product Code (UPC) barcode
- QR Code graphic

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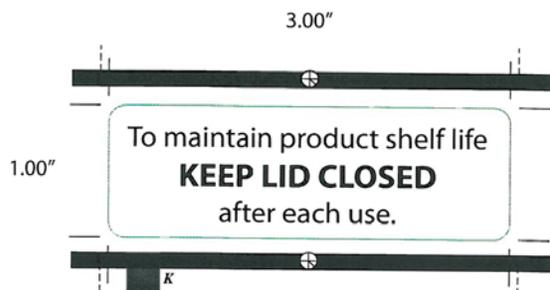
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- Not a baby wipe pictogram



ENGLISH-SPANISH

- “To maintain product shelf life KEEP LID CLOSED after each use” pictogram



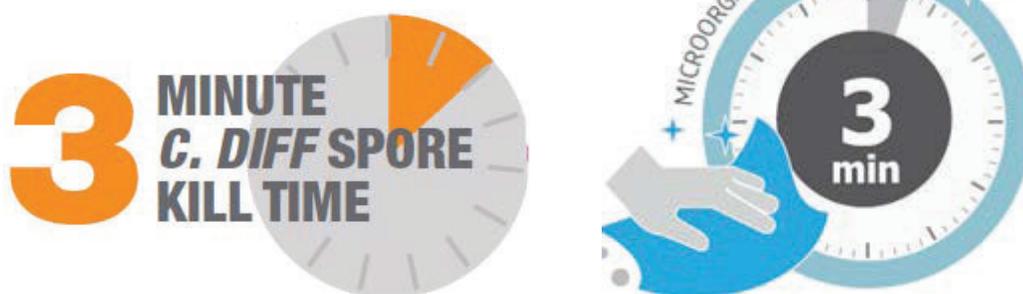
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- Ship and store this end up pictogram



- 3-Minute Contact Time pictogram



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- Microorganisms logo



- Made in the USA



- Not for use on skin logo

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{Sub Label B: Refill Container/Pouch}

For refilling [Product Name]

MICRO-KILL BLEACH GERMICIDAL BLEACH WIPES [Product Name]

[Alternate Brand Name: Micro-Kill Bleach Wipes, Micro-Kill Bleach Germicidal Bleach Wipes & Bucket, Micro-Kill Bleach Wipes & Bucket, Micro-Kill Bleach Germicidal Wipes, Micro-Kill Disinfectant Bleach Wipes]

Active Ingredient:	
Sodium hypochlorite.....	0.65%
Other Ingredients ~:.....	<u>99.35%</u>
Total	<u>100.00%</u>

~Other ingredients do not include the weight of towelette.

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] [pouch] [label] for [first aid statement] [,] [precautionary statements] [,] [and] [storage and disposal])]

EPA Reg. No. 37549-1
EPA Est. No. xxxxx-xx-xxx
[DIN: #]
U.S. Patent No. xxxxx
Net Contents [xx.xx] oz.

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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 FILLING] [TO FILL] [TO FILL OR REFILL] CONTAINERS [SOLD SEPARATELY]
{OR}**

[FOR REFILLING] [TO REFILL] [FOR FILLING OR REFILLING] CONTAINERS [SOLD SEPARATELY]

1. Always use personal protective equipment. {AND/OR}Wear gloves when handling this product.
2. To [re]fill the canister with towelettes cut open sealed pouch and place the roll of towelettes into the canister.

OR

To fill or refill the bucket with towels, place the sealed pouch containing the roll of towels in the bucket and then cut open the pouch.

OR

To fill or refill the bucket with towels, cut open the sealed pouch containing the roll of towels and then place the open pouch in the bucket.

3. Pull up corner of center towelette [and] [,] snap off [,] and discard. Take the next towelette [and] [,] [twist to a point] [and thread] [before] [prior to] [then] [thread] [threading] through dispenser hole in lid.
4. **DO NOT PUSH FINGER THROUGH OPENING**
5. Replace lid. Pull out exposed towelette [to perforation] and snap off [at a 90° angle]. The next towelette pops up automatically.
6. Snap center flap down when finished to retain moisture.
7. Do not flush towelette [into] [down the] [toilet].
8. Refer to [label on the] canister 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 preclean 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 and 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.

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STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry, and well-ventilated area away from heat, open flame, direct sunlight and inaccessible to children.

Pesticide Disposal: [Wastes resulting from the use of [Product name] [these towelettes] must be disposed of [on site] [in the trash] [or] [at an approved waste disposal facility]. [Dispose of [used] towelettes in the trash] [after use]. [Do not flush towelette [into] [down the] toilet.]

Container Handling: Nonrefillable pouch. Do not re-use or refill this pouch. Completely empty contents of pouch into canister, then offer [empty pouch] for recycling if available or discard in trash.

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
- Contains 0.65% available chlorine.
- Contains 0.65% [active] sodium hypochlorite.
- [Contains] [Solution of] 0.65% bleach

- Distributed by [:] [company name]
- Disposable

- [Expiration date] [EXP] [EXP DATE] [XXXXXX]

- For complete product line information, call [company name]
- For refilling [Product Name]

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- 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 [XXXXXXXX]
- Protect from freezing.
- [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.
- Presaturated towel
- Premoistened [3” x 3”] [3” x 4”] [5” x 9”] [6” x 6”] [6” x 7”] [6” x 8”] [6” x 9”] [7” x 8”] [7” x 9”] [8” x 7”] [8” x 9”] [8” x 10”] [9” x 6”] [9” x 9”] [12” x 12”] [14” x 14”] [9” x 12”] [12” x 9”] [X” x X”] Towelette [CAT#XXXX]

- [Ready to use] [RTU]
- Ready to Use [hospital [use] disinfectant.
- Ready to use EPA registered hospital disinfectant.
- Ready to use EPA registered [hospital] [use] [disinfectant] [bleach wipe[s]].
- Refill[s] for [Product Name]
- Rotate dated product[s] while in inventory.

- Shield from direct sunlight.
- Shelf-stable formula.
- Suitable for use on hard, non-porous [inanimate] [environmental] [and] [healthcare] surfaces.
- Sold by [:] [Company Name]
- Store at room temperature or cooler for best product performance.

{Optional Foreign Language Phrases}

English: Made In U.S.A.

Spanish: [Hecho en los Estados Unidos]

English: Use on hard, non-porous surfaces only. Not a skin wipe. Not a baby wipe.

Spanish: Utilizar solo en superficies duros non-porous. No es paño limpiador para la piel. No es toallita de bebé.

English: Use on hard, non-porous surfaces only

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Spanish: Utiliza solamente non-porous en superficies duros.

English: Not for use on skin

Spanish: No para uso sobre la piel

French: A ne pas utiliser sur la peau

English: Not a skin wipe

Spanish: No es una toalla para la piel

English: Not a baby wipe or adult wipe

Spanish: No es una toalla para los bebés o toalla para adultos

English: It is prohibited to use as a wipe for babies or adults

Spanish: Es prohibido utilizar como una toalla para los bebés o adultos

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

- Barcode
 - DOT graphic
 - Universal Product Code (UPC) barcode
 - QR Code graphic
-
- Not a baby wipe pictogram

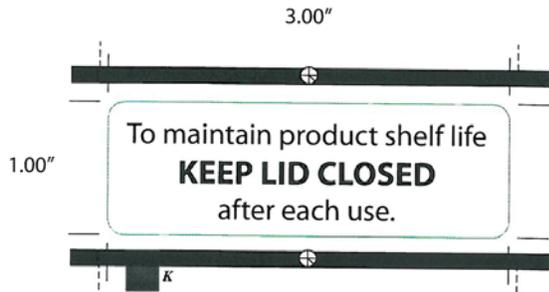


ENGLISH-SPANISH

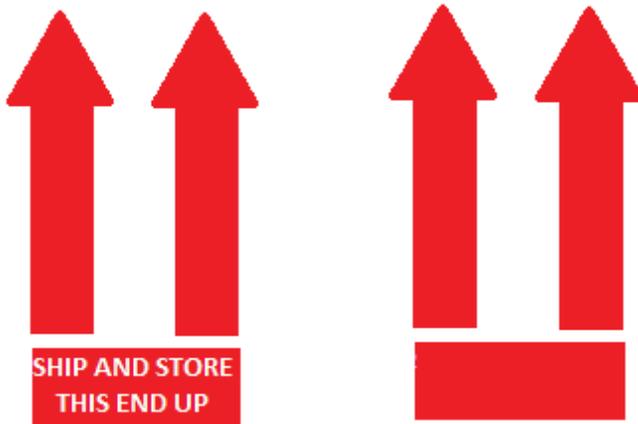
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- “To maintain product shelf life KEEP LID CLOSED after each use” pictogram



- Ship and store this end up pictogram



- Made in the USA



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- Not for use on skin logo



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- Contact Time pictogram {representative – may be used with organism and corresponding contact time from Directions for Use}



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- Microorganisms logo

