

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 15, 2022

Abigail T.D. Wacek Authorized Representative Medline Industries, Inc. Three Lakes Drive Northfield, IL 60093

Subject: PRIA Label Amendment – Addition of public health organisms Product Name: Micro-Kill Bleach Germicidal Bleach Solution EPA Registration Number: 37549-1 Received Date: 7/23/2021 Action Case Number: 00313451

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 Melanie Bolden by phone at (202) 566-0674, or via email at Bolden.Melanie@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: "towelette(s)", "towel(s)", "wipe(s)", "wiper(s)" and "cloth(s)"; "Premoistened", "Premeasured", "Convenient", "Disposable", "Saturated" and "Pre-saturated"; "Glucometers", "Glucose Meters", and "Blood Glucose Meter"; "Container", "canister", "tub", "pail" and "bucket"; "bag", "pouch", "packet", "sachet", and "refillables"; "Bleach", "NaOCl" and "sodium hypochlorite"; "This Product", "These Products", "These wipes", "This wipe," 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.}

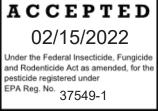
{Sub Label A: Ready to Use Wipes}

# [MEDLINE] MICRO-KILL BLEACH GERMICIDAL BLEACH WIPES [Product Name]

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

These wipes [are] 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 <sup>~</sup> :	<u>99.35%</u>
Total	100.00%
<sup>~</sup> 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 [(Lot code letters indicate establishment number.)] [DIN: #] U.S. Patent No. xxxxx Net Contents [xx.xx] oz.

### **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. Visible soil must be removed from surfaces prior to disinfecting.
- 3. Open [Product Name] [packet] [canister].
- 4. Remove premoistened [X" x X"] towelette.
- 5. Apply [premoistened] towelette and wipe desired surface to be disinfected. {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}



{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].

• **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.

<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 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 Disposa**l: [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.

*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, LP 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] {Note to reviewer: The following list of micro-organisms may be in table or list format.}

[Efficacy Claims]

[Pathogen][Micro-organism][Microbe]Name	Source	Contact Time
*SPORICIDAL / SPORES 3 minute[s] contact time		
Clostridium difficile [C. difficile] [C. diff] spores*	[ATCC 43598]	3 minute[s]
**VIRUCIDAL / VIRUSES 30 second[s] contact time		
[SMALL NON-ENVELOPED VIRUSES]		
Canine Parvovirus	[ATCC VR-2017]	30 second[s]
Enterovirus [Type] D68 [Strain US/KY/14-18953]	[ATCC VR-1825]	30 second[s]
Feline Panleukopenia Virus [Feline Parvovirus]	[ATCC VR-648]	30 second[s]
Hepatitis A Virus [(]HAV[)]	[HM-175]	30 second[s]
Norovirus [(Feline Calicivirus)] [Norwalk Virus]	[ATCC VR-782]	30 second[s]
Poliovirus (Type 1)	[ATCC VR-1562]	30 second[s]
Rhinovirus (Type 37)	[ATCC VR-1147]	30 second[s]
[LARGE NON-ENVELOPED VIRUSES]		
Adenovirus Type 5 [Adenovirus]	[ATCC VR-5]	30 second[s]
Rotavirus	[ATCC VR-2018]	30 second[s]
[ENVELOPED VIRUSES]		
Avian Influenza A Virus (H3N2)	[ATCC VR-2072]	30 second[s]
Avian Influenza A Virus (H5N1)	[CDC 2006719965]	30 second[s]
Avian Influenza A Virus (H7N9)	[CDC 2013759189]	30 second[s]
Cytomegalovirus [CMV] (Strain AD-169)	[ATCC VR-538]	30 second[s]
Herpes Simplex Virus Type 2 [(]HSV-2[)]	[ATCC VR-734]	30 second[s]
Human Coronavirus	[ATCC VR-740]	30 second[s]
Influenza A Virus (H1N1)	[CDC 2009712192]	30 second[s]
Influenza A Virus	[ATCC VR-544]	30 second[s]
Influenza B Virus (Strain B)	[ATCC VR-823]	30 second[s]
Respiratory Syncytial Virus [(]RSV[)]	[ATCC VR-26]	30 second[s]
SARS-Related Coronavirus 2 [SARS-CoV-2]	[USA-WA1/2020]	30 second[s]
Vaccinia Virus (Strain WR)	[ATCC VR-119]	30 second[s]
[ENVELOPED VIRUSES] [BLOODBORNE PATHOGENS]		
+Hepatitis B Virus [(DHBV)] [(]HBV[)]		30 second[s]
+Hepatitis C Virus [(BVDV)] [(]HCV[)]		30 second[s]
+Human Immunodeficiency Virus Type 1 [(]HIV-1[)] [HTLV-IIIB] [Aids Virus]		30 second[s]
[ANIMAL VIRUSES]		
Bovine Viral Diarrhea Virus [(]BVDV[)] [(]HCV[)]		30 second[s]
Duck Hepatitis B Virus [(]DHBV[)] [(]HBV[)]		30 second[s]

[Pathogen][Micro-organism][Microbe]Name	Source	Contact Time	
Feline Calicivirus	[(]ATCC VR- 782[)]	30 second[s]	
BACTERICIDAL / BACTERIA 30 second[s] contact time			
[DRUG-RESISTANT BACTERIA]			
Acinetobacter baumannii – MDR [(]A. baumannii-MDR[)] [[MultidrugResistant [(MDR)] [Acinetobacter baumannii] [A. baumannii]]	[ATCC 19606]	30 second[s]	
Community Acquired- [CA-] Methicillin-Resistant Staphylococcus aureus [S. aureus] [CA-MRSA] [Genotype USA400]	5 [NRS 123]	30 second[s]	
Enterococcus faecium-MDR [(]E. faecium-MDR[)] [Multidrug res [(MDR)] [Enterococcus faecium] [E. faecium] [MDR [(Multidrug resistant)] [Enterococcus faecium] [E. faecium]	istant [ATCC 51559]	30 second[s]	
Escherichia coli-ESBL [ESBL] [(Extended Spectrum Beta-Lactam producing [Escherichia coli] [(]E. coli[)] [Extended Spectrum Beta Lactamase [(ESBL)] producing [Escherichia coli] [(]E coli[)]	/3 2 3	30 second[s]	
Klebsiella pneumoniae-CRKP [(]CRE[)] [(][Carbapenem resistant Enterobacteriaceae][)] [(CRE)] [Carbapenem resistant Klebsiella pneumoniae [(CRKP)] {Note to reviewer: The following statement required with use of CRE – Klebsiella pneumoniae is a member of family Enterobacteriaceae.}		30 second[s]	
Enterococcus faecalis –VRE [Vancomycin-Resistant Enterococcus faecalis] [VRE]	[ATCC 51575]	30 second[s]	
Escherichia coli-NDM-1 [(]E. coli-NDM-1[)] [[Escherichia coli] [( coli)] [New Delhi Metallo- Beta-Lactamase-1] [(]NDM-1[)] [Escherichia coli] [(]E. coli[)]	E. [CDC 1001728]	30 second[s]	
Klebsiella pneumoniae-ESBL [ESBL [(Extended Spectrum Beta- Lactamase)] producing [Klebsiella pneumoniae] [(]K. pneumoniae [Extended Spectrum beta-Lactamase [(ESBL)] producing [Klebsie] pneumoniae] [(]K. pneumoniae[)]		30 second[s]	
Klebsiella pnuemoniae-NDM-1 [(]K. pneumoniae-NDM-1[)] [Klebsiella pneumoniae] [(]K. pneumoniae[)] [New Delhi Metallo- Lactamase-1] [(]NDM-1[)] [[NDM-1 [Klebsiella pneumoniae] [(]K pneumoniae[)]	Beta [CDC 1000527]	30 second[s]	
Linezolid Resistant Staphylococcus aureus [(]LRSA[)]	[NRS 119]	30 second[s]	
Methicillin Resistant Staphylococcus aureus [(]MRSA[)]	[ATCC 33592]	30 second[s]	
Staphylococcus aureus-VISA [Vancomycin-Intermediate Staphylococcus aureus] [VISA]	[ATCC HIP 5836]	30 second[s]	
Staphylococcus aureus –VRSA [Vancomycin-Resistant Staphyloco aureus] [VRSA]	occus [VRS1]	30 second[s]	
[BACTERIA]			
Bordetella pertussis [(]B. pertussis[)]	[ATCC 12743]	30 second[s]	
Campylobacter jejuni [(]C. jejuni[)]	[ATCC 29428]	30 second[s]	
Enterobacter aerogenes [(]E. aerogenes[)]	[ATCC 13048]	30 second[s]	
Enterobacter cloacae [(]E. cloacae[)]	[ATCC 13047]	30 second[s]	
Escherichia coli [(]E. coli[)]	[ATCC 11229]	30 second[s]	

[Pathogen][Micro-organism][Microbe]Name	Source	Contact Time
Escherichia coli O157:H7 [(]E. coli O157:H7[)]	[ATCC 35150]	30 second[s]
Klebsiella pneumoniae [(]K. pneumoniae[)]	[ATCC 4352]	30 second[s]
Legionella pneumophila [(]L. pneumophila[)] [(]Legionella[)]	[ATCC 33153]	30 second[s]
Listeria monocytogenes [(]L. monocytogenes[)] [(]Listeria[)]	[ATCC 19117]	30 second[s]
Neisseria gonorrhoeae [N. gonorrhoeae]	[ATCC 43069]	30 second[s]
Proteus mirabilis [(]P. mirabilis[)]	[ATCC 9240]	30 second[s]
Pseudomonas aeruginosa [(]P. aeruginosa[)]	[ATCC 15442]	30 second[s]
Salmonella enterica	[ATCC 10708]	30 second[s]
Serratia marcescens	[ATCC 14756]	30 second[s]
Shigella dysenteriae	[ATCC 11835]	30 second[s]
Staphylococcus aureus	[ATCC 6538]	30 second[s]
Streptococcus pneumoniae	[ATCC 6305]	30 second[s]
Streptococcus pyogenes	[ATCC 19615]	30 second[s]
FUNGICIDAL / FUNGI 1 minute contact time		
Candida albicans [(]C. albicans[)]	[ATCC 10231]	1 minute
Trichophyton interdigitale [(Organism that causes Athlete's Foot	[ATCC 9533]	1 minute
Fungus)]		
***FUNGICIDAL / FUNGUS 2 minute[s] contact time		
Candida auris [(]C. auris[)]	[(]CDC AR-0381[)]	2 minute[s]

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.}				
– Airplanes	<ul> <li>Home healthcare sites</li> </ul>	<ul> <li>Physical therapy offices</li> </ul>		
– Aviation	<ul> <li>Hospital laboratory[ies]</li> </ul>	<ul> <li>Physician offices</li> </ul>		
– Bathroom[s]	[lab[s]	<ul> <li>Police stations</li> </ul>		
– Cafeterias	– Hospitals	<ul> <li>Poultry houses</li> </ul>		
– Clean rooms	– Hotels	<ul> <li>Radiology rooms</li> </ul>		
<ul> <li>Clinical laboratory[ies]</li> </ul>	– Houses	<ul> <li>Recovery room</li> </ul>		
[lab[s]	– ICU/CCU	<ul> <li>Recreation centers</li> </ul>		
– Churches	<ul> <li>ISO9000 environments</li> </ul>	<ul> <li>Rehabilitation facilities</li> </ul>		
– Colleges	<ul> <li>Janitorial surfaces</li> </ul>	<ul> <li>Renal dialysis rooms</li> </ul>		
– Cruise ships	<ul> <li>Kitchen[s]</li> </ul>	<ul> <li>Rest rooms</li> </ul>		
<ul> <li>Day Care Centers</li> </ul>	<ul> <li>Laboratories</li> </ul>	– Restaurants		
<ul> <li>Dental laboratory[ies]</li> </ul>	<ul> <li>Laundromats</li> </ul>	– Schools		
[lab[s]	<ul> <li>Laundry rooms</li> </ul>	<ul> <li>School buses</li> </ul>		
<ul> <li>Dental offices</li> </ul>	<ul> <li>Locker rooms</li> </ul>	– Shelters		
<ul> <li>Doctor's offices</li> </ul>	<ul> <li>Medical laboratory[ies]</li> </ul>	<ul> <li>Shower rooms</li> </ul>		
– Dormitories	[lab[s]	<ul> <li>Skilled long term care</li> </ul>		
<ul> <li>Emergency medical sites</li> </ul>	<ul> <li>Mortuaries</li> </ul>	facility[ies]		
<ul> <li>Emergency rooms</li> </ul>	– Motels	<ul> <li>Skilled nursing facility</li> </ul>		
– EMS sites	<ul> <li>Nursery schools</li> </ul>	[SNF]		
<ul> <li>Extended care facilities</li> </ul>	<ul> <li>Nursing stations</li> </ul>	<ul> <li>Supermarkets (non-food</li> </ul>		
<ul> <li>Farm premises</li> </ul>	<ul> <li>Nursing homes</li> </ul>	contact surfaces)		
– Fire stations	<ul> <li>Nursing homes</li> </ul>	– Surgeries		
<ul> <li>General nursing stations</li> </ul>	<ul> <li>Nursing stations</li> </ul>	– Universities		
<ul> <li>General stores</li> </ul>	– Offices	<ul> <li>Veterinarian clinics</li> </ul>		
– Gymnasiums	<ul> <li>Out patient care clinics</li> </ul>			
– Health clubs	<ul> <li>Pediatric offices</li> </ul>			

# For use on hard, non-porous, nonfood contact of the following Surfaces:

{Note to reviewer: These surfaces to be used where indicated in claims.}			
– [Blood] glucose meters†	– Faucets	<ul> <li>Plastic mattress covers</li> </ul>	
– Appliances	– Floors	– Plastics	
<ul> <li>Ambulance equipment</li> </ul>	<ul> <li>Flush handles</li> </ul>	– Playpens	
<ul> <li>Bar code readers</li> </ul>	– Formica	– Plexiglas	
– Bathtubs	- Freezers (exterior surfaces)	<ul> <li>Point-of-care equipment</li> </ul>	
<ul> <li>Bathroom handrails</li> </ul>	– Garbage cans	<ul> <li>Room temperature control</li> </ul>	
<ul> <li>Bathroom fixtures</li> </ul>	– Glass	knobs	
<ul> <li>Bed pan[s]</li> </ul>	<ul> <li>Glazed [ceramic] tiles</li> </ul>	– Showers	
– Bed rails	<ul> <li>Glazed tile walls</li> </ul>	<ul> <li>Shower head control knobs</li> </ul>	
<ul> <li>Bedside commodes</li> </ul>	<ul> <li>Glazed porcelain</li> </ul>	<ul> <li>Shower fixtures</li> </ul>	
<ul> <li>Bedside tables</li> </ul>	– Glucometers†	<ul> <li>Shower stall(s)</li> </ul>	
<ul> <li>Bedside testing equipment</li> </ul>	<ul> <li>Hand railings</li> </ul>	– Sinks	
<ul> <li>Biological safety [cabinets]</li> </ul>	<ul> <li>Hard plastic surfaces</li> </ul>	<ul> <li>Sink tops</li> </ul>	
– [hood]	– Headsets	<ul> <li>Sphygmomanometers</li> </ul>	
<ul> <li>Cabinet handles</li> </ul>		<ul> <li>Stainless steel</li> </ul>	

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

Stains Table			
{Note to reviewer: These stains/soils	to	be u	se
– Blood	_	G	rea

{Note to reviewer: These stains/soils	to be used where indicated in claims.	}
– Blood	– Grease	<ul> <li>Organic matter</li> </ul>
<ul> <li>Coffee stains</li> </ul>	– Grime	<ul> <li>Tea stains</li> </ul>
– Dirt	<ul> <li>Laboratory stains</li> </ul>	– Urine
– Fecal matter	<ul> <li>Common soils</li> </ul>	
– Fingerprints	<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 hard 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, 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.
- 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]
- 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<sup>†</sup>.
- [Can be used] [For use] to disinfect hard, non-porous surfaces of glucometers <sup>†</sup>, [and] [stethoscopes] [and] [sphygmomanometers] [in glucometer<sup>†</sup> 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* [(]CRE[)].
- Carbapenem Resistant Klebsiella pneumoniae [(CRKP)][or] [-] [(CRE)]
- Cleans, disinfects, and deodorizes.
- Company Name [Lot Number] [Lot xxxxx]
- 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<sup> $\dagger$ </sup>.
- Clostridium difficile spores\*
- Convenient, Pre-Saturated Disposable towelette.
- Convenient, Disposable Pre-Saturated towelette.
- Cost Savings[:]
- Daily use [this] product with [disinfectant with sporicidal\* activity against *C. diff*.] [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], [disinfectant with sporicidal\* activity against *C*. *diff*.], [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 flush] [Do Not Flush]
- 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].
- [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 *C. diff* spores] [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.
- 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 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 disinfection of] [For disinfecting] [Disinfects] [Glucometers<sup>†</sup>] [,] [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 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.
- 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.
- Kills Influenza A Virus, commonly associated with the 2009 H1N1 Pandemic.
- Kills Influenza A Virus, commonly associated with 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 [organism name] in [contact time] [on hard, non-porous surfaces] [in [use site]]. {Note to reviewer: Use site comes from aforementioned Use Sites list. Organism name and contact time come from aforementioned Efficacy Claim list.}
- Kills C. diff. spores in 3 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 [99.999% of] SARS-CoV-2 [virus] on hard, non-porous surfaces in [just] 30 seconds!
- 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]
- 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] [disinfectant with sporicidal\* activity against *C. diff*], [virucidal\*\*], [bactericidal] [and] [fungicidal\*\*\*].
- One-step^ [cleaner [and] disinfectant] [disinfectant [and] cleaner] [cleaning and disinfecting] [bleach] wipe[s].
- One-step^ [antimicrobial], [disinfectant with sporicidal\* activity against *C. diff*] [virucidal\*\*], [bactericidal], [fungicidal\*\*\*], disinfectant wipe[s].
- [One-step^] [cleaner and disinfectant] bleach wipe[s].
- [Packaged] [Packed] for [XXXXXX]
- Penetrates and breaks down [dust mite particles] [,] [cockroach particles] [and] [pet dander] [allergens] [found in dust].
- Preclean prior to disinfecting hard, non-porous surfaces for [+HCV] [,] [+HIV-1] [and] [+HBV] [and] [,] [*Clostridium difficile* spores\*] [and] [*Candida auris*\*\*\*].
- Premoistened [X" x X"] Towelette
- [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<sup>†</sup>, 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] [EPA Registration Number 37549-1] [has a] [with a] *Clostridium difficile* spore\* kill claim with [a] 3 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 37549-1] [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 37549-1] [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 37549-1] [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] [bleach] [wipes] [were] [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] [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][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] [disinfectant with sporicidal\* activity against C. diff] [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] [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 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] [is] [are] [a] one-step^ [cleaning] [cleaner] and [disinfecting] [disinfectant] wipe[s].
- [Product Name] is used [as] [for] [to]
- [Product Name] is a disinfectant with sporidical\* activity against *C. diff* bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is a bactericidal bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is a fungicidal\*\*\* bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is a virucidal\*\* bleach wipe cleaner, deodorizer, disinfectant.
- [Product Name] is an 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<sup>†</sup>.
- [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, nonporous 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] 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 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 [Ready to Use] [as] sporicidal\* 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 [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 [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
- 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.
- Proven to kill the SARS-CoV-2 virus that causes COVID-19 on hard non-porous surfaces.
- [Ready to use] [RTU] [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\*, 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.
- [Tested] [and] proven to kill SARS-CoV-2 on hard, non-porous surfaces.
- The convenient way to clean and disinfect with [Product Name].
- 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. Visible 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 disinfectant with sporicidal\* activity against *C. diff*, 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\*\*
- Visible soil must be removed prior to disinfecting.
- 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.
- 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

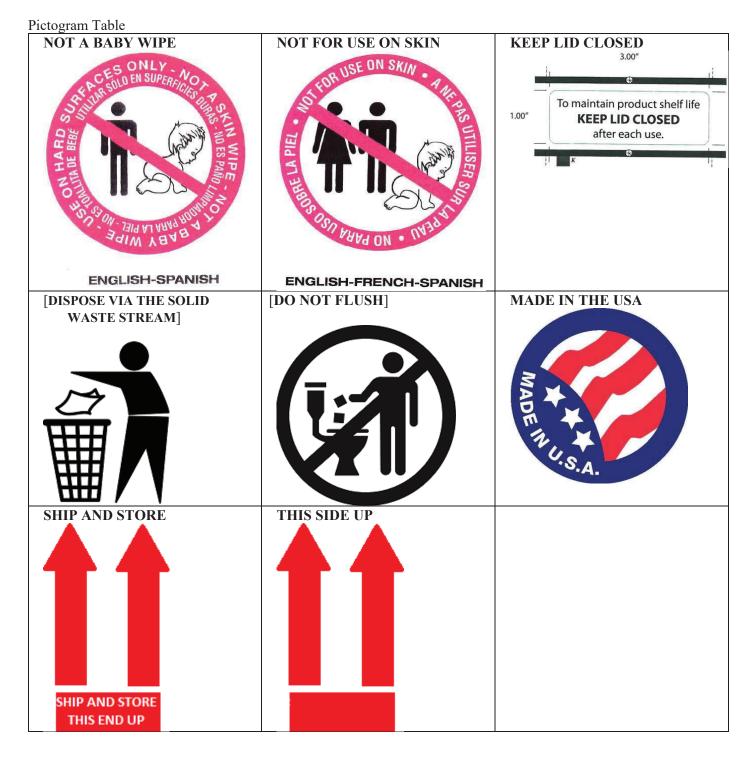
English: Not a skin wipe Spanish: Noes una toalla para la piel

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

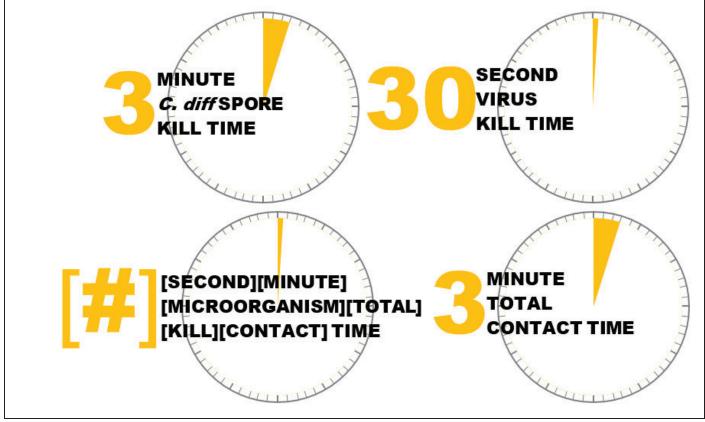
The following pictograms are for optional inclusion to the [Product Name] product label:

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



## CONTACT TIME

*{NOTE TO REVIEWER: Clock-like pictogram with overlay or surrounding language to include specific microorganism or general term for microorganisms and corresponding contact time. Wording maybe be stylized in different ways to ensure it is inclusive of the image. See below for a few examples.}* 



For refilling [Product Name]

# [MEDLINE] MICRO-KILL BLEACH GERMICIDAL BLEACH WIPES [Product Name]

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

Active Ingredient:	
Sodium hypochlorite	0.65%
Other Ingredients <sup>~</sup> :	<u>99.35%</u>
Total	100.00%
<sup>~</sup> 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 (Lot code letters indicate establishment number.) [DIN: #] U.S. Patent No. xxxxx Net Contents [xx.xx] oz.

### **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.

#### 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 Disposa**l: [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, LP 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}**

*{Note to reviewer: Any of the optional additional text from Sub-Label A may be used in addition to the one from below.}* 

- 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-xxxx] [contacting]: xxx-xxxx
- Contains 0.65% available chlorine.
- Contains 0.65% [active] sodium hypochlorite.
- [Contains] [Solution of] 0.65% bleach
- Distributed by [:] [company name]
- Disposable
- [Do not flush] [Do Not Flush]
- [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 xxxxx]
- 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]
- 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 [X" x X"] [Towelette] [CAT#XXXX]
- [Ready to use] [RTU]
- Ready to Use [hospital [use] disinfectant.
- Ready to use [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.

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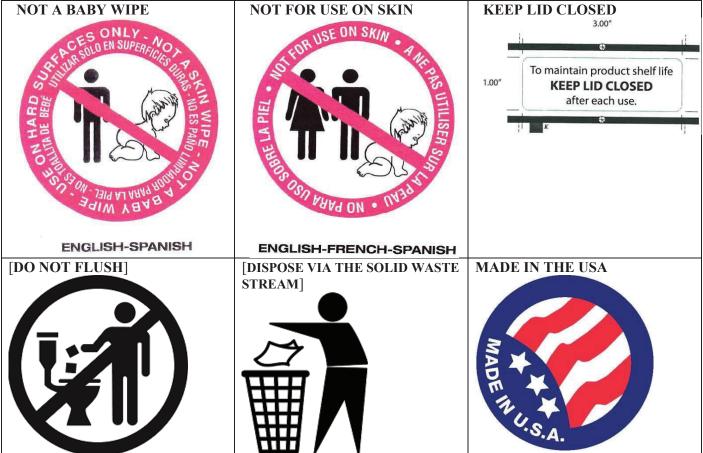
English: Not a baby wipe or adult wipe Spanish: No una toalla para los bebé's o toalla para adultos

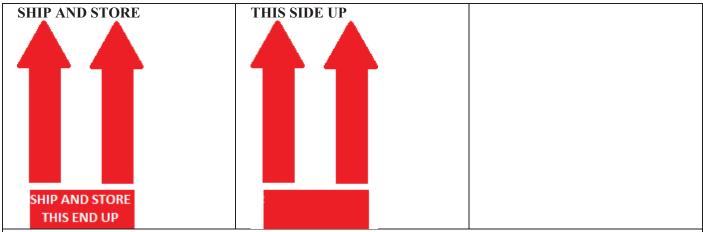
English: It is prohibited to use as a wipe for babies or adults Spanish: Es prohibido a utilizar como una toalla para los bebé's o adultos

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

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

Pictogram Table





### **CONTACT TIME**

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