

# **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

# AUG 1 4 2013

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Julie Timberman Sr. Regulatory Scientist Clorox Professional Products Company c/o PS&RC; P.O. Box 493 Pleasanton, CA 94566-0803

Subject:

Dispatch® Hospital Cleaner Disinfectant Towels with Bleach

EPA Registration No.: 56392-8 Application Date: 04/16/2013 EPA Receipt Date: 04/19/2013

Dear Ms. Timberman:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable.

# **Proposed Amendment**

- Addition of Home Healthcare language along with minor label revisions
- Alternate Brand Names:
  - o Clorox® CareConcepts<sup>TM</sup> Germicidal Bleach Wipes
  - o CareConcepts<sup>TM</sup> Germicidal Bleach Wipes
  - o Remeda Germicidal Bleach Wipes
  - o Clorox® CareConcepts<sup>TM</sup> Disinfecting Bleach Wipes
  - o CareConcepts<sup>TM</sup> Disinfecting Bleach Wipes
  - o Remeda Disinfecting Bleach Wipes
  - o Clorox® CareConcepts<sup>TM</sup> Germ Control Kit (containing Clorox® CareConcepts<sup>TM</sup> Germicidal Bleach Wipes)
  - o CareConcepts<sup>TM</sup> Germ Control Kit (containing CareConcepts<sup>TM</sup> Germicidal Bleach Wipes)
  - o Remeda Germ Control Kit (containing Remeda Germicidal Bleach Wipes)
  - o Clorox® CareConcepts<sup>TM</sup> Germ Control Kit (containing Clorox® CareConcepts<sup>TM</sup> Disinfecting Bleach Wipes)
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  - o Remeda Germ Control Kit (containing Remeda Disinfecting Bleach Wipes)
  - o Clorox® CareConcepts<sup>TM</sup> Germ Disinfection Kit (containing Clorox® CareConcepts<sup>TM</sup> Germicidal Bleach Wipes)
  - o CareConcepts<sup>TM</sup> Germ Disinfection Kit (containing CareConcepts<sup>TM</sup> Germicidal Bleach Wipes)

- o Remeda Germ Disinfection Kit (containing Remeda Germicidal Bleach Wipes)
- o Clorox® CareConcepts<sup>TM</sup> Germ Disinfection Kit (containing Clorox® CareConcepts<sup>TM</sup> Disinfecting Bleach Wipes)
- o CareConcepts<sup>TM</sup> Germ Disinfection Kit (containing CareConcepts<sup>TM</sup> Disinfecting Bleach Wipes
- o Remeda Germ Disinfection Kit (containing Remeda Disinfecting Bleach Wipes)

## **General Comments**

A stamped accepted label with conditions is enclosed for your records. This labeling supersedes all previous labeling. The next printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed label before selling or distributing the product bearing the revised 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 it's implementing regulation at 40 CFR 152.3.

Should you have any questions or comments concerning this letter, you may contact Jaclyn Pyne by telephone at (703) 347-0213 or by e-mail at pyne.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Demson Fuller

Acting Product Manager (32)

Regulatory Management Branch II Antimicrobials Division (7510P)



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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Julie Timberman Sr. Regulatory Scientist Clorox Professional Products Company c/o PS&RC; P.O. Box 493 Pleasanton, CA 94566-0803

Subject:

Clorox Home Health Care Concepts Kits

EPA Registration Nos: 5813-105, 56392-8, 67619-26

Dear Ms. Timberman:

This correspondence is to acknowledge the kit language and formatting with the stamped labels dated August 14, 2013 for the registrations referenced above. The placement of the ingredient statement on kit packaging is acceptable on the back panel with the rest of the product-specific information. The kit graphics and inserts have been reviewed by EPA for consistency with the master label, even though they will not be stamped as part of the label. The kit itself does not need its own registration and EPA allows registrants the option of using alternate brand names for each of the existing registrations of the products inside the kit. Each alternate brand name identifies the product as part of the kit, but is unique.

Should you have any questions or comments concerning this letter, you may contact Jaclyn Pyne by telephone at (703) 347-0213 or by e-mail at pyne.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely

Demson/Fuller

Acting Product Manager (32)

Regulatory Management Branch II

Antimicrobials Division (7510P)

Note: Bold, italicized text is information for the reads, and is not part of the label.

[Bracketed information is optional text.] Green underlined text is new. Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. R0887059 clean Rosie

# **DISPATCH®**

# **Hospital Cleaner Disinfectant Towels with Bleach**

# KEEP OUT OF REACH OF CHILDREN CAUTION

NOT TO BE USED AS BABY WIPES
KEEP PACKAGE -OR- CONTAINER TIGHTLY SEALED WHEN NOT IN USE
Read Complete Directions and Precautions on Back -or- side -or- rear
[Panel[s]] [Dispenser Carton]
SELECT A SIZE (For Canister Only)

[Net] [Contents] [# of towels and size and weight]
Each package type and size will bear the actual net contents in pounds and ounces

ACCEPTED

AUG 14 2013

Under the Federal Insecticidal Fungicide, and

Under the Federal Insecticida, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under

- [Contains 6500 ppm Sodium Hypochlorite]
- [Cleans [and], Disinfects, [& Deodorizes] in One Step]
- [Kills [99.99% of] bacteria, viruses† & fungi in 1 Minute on Hard, Nonporous Surfaces]
- [Kills Pandemic 2009 H1N1 Influenza A Virus]
- [Kills Clostridium difficile [spores] in 5 Minutes [on Precleaned, Hard, Nonporous Surfaces][\*],###
- [Peel and Reseal Here for flex packs only]
- [Pre-Moistened Towels with 1:10 Dilution of Bleach [(6.0%)] and Detergent]

Kills [99.99% of] bacteria, viruses† & fungi in 1 Minute [on Hard Non-Porous Surfaces], [(see rear panel)]: Acinetobacter baumannii, †Avian Influenza A Virus, †Canine Parvovirus, Enterobacter aerogenes, Escherichia coli ESBL, †Feline Panleukopenia Virus, †Hepatitis A Virus (HAV), †Hepatitis B Virus (HBV)†††, †Hepatitis C Virus (HCV)†††, †Herpes Simplex Virus (HSV-2), †HIV-1 (AIDS Virus)†††, †Influenza A H1N1 [2009] [Pandemic], †Influenza A Virus, Klebsiella pneumoniae, [Methicillin resistant] Staphylococcus aureus (MRSA), †Norovirus, †Poliovirus Type 1 (Mahoney), Pseudomonas aeruginosa, †Rhinovirus, †Rotavirus, Salmonella enterica tested as Salmonella choleraesuis, Staphylococcus aureus, Streptococcus pyogenes, Trichophyton mentagrophytes (Athlete's Foot Fungus), [Vancomycin resistant] Enterococcus faecalis (VRE)

Kills Mycobacterium bovis-BCG, (TB) in 2 Minutes

Kills Clostridium difficile ### [spores] in 5 minutes [on Precleaned, Hard, Nonporous Surfaces ][\*]

Manufactured for:

© XXXX Clorox Professional Products Company

1221 Broadway, Oakland, CA 94612

[QUESTIONS OR COMMENTS?] [Call] 800-234-7700

[Visit us at -or- For MSDS information, [please] go to] www.cloroxprofessional.com

A list of this product's ingredients is available at www.lngredientsInside.com -or-

A list of [this product's] [product name] ingredients is available at

[insert company website].

Clorox is a registered trademark of the Clorox Company

insert trademark is a [registered] trademark of Clorox Professional Products Company

EPA Reg. No. 56392-8 EPA Est. No. 8251-OH-1 (Q6); 5813-GA-2 (VG); IL-2 (VF) Beginning of batch code indicates Est. No.

ttt Note to reviewer: not to be included for "Home Healthcare" product or kit labeling

[Bracketed information is optional text.] <u>Green underlined text is new.</u> Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. R0887059\_clean\_Rosie

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Disinfectant Towels with Bleach
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# PRECAUTIONARY STATEMENTS: Hazards to humans and domestic animals. CAUTION:

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

### FIRST AID:

If in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. If present, remove contact lenses after the first 5 minutes of rinsing, then continue rinsing eye. Call a poison control center or doctor for further treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [Emergency Information: 1-800-446-1014. -or- Poison Control Center: (800) 446-1014 -or- Clorox Information Line: 1-888-797-7225 -or- Questions? Call 1-888-797-7225.]

### PHYSICAL OR CHEMICAL HAZARDS

Do not use this product with ammonia or acids such as vinegar, rust removers, or toilet bowl cleaners.

## STORAGE AND DISPOSAL:

### For canisters

Store this product in a cool, dry area away from direct sunlight and heat. When not in use keep center cap of lid closed to prevent moisture loss. Nonrefillable container. Do not reuse or refill this container. Discard used towels and container in trash or take container to recycling center. [Do not flush towels down toilet.]

# For soft packs and individually wrapped packs

Store this product in a cool, dry area away from direct sunlight and heat. Nonrefillable container. Do not reuse or refill this container. Discard used towel and empty package in trash. [Do not flush towels down toilet.]

R0887059\_clean\_Rosie.indd 2

## **Packaging Related Statements**

## For fold-pack labels:

Peel for [here] [additional] directions [for use][.]

Dispenser:

### Canister

To open: Remove lid. Discard inner seal from canister.

**To thread:** Find center of wipe roll, twist corner of first wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out and tearing off. When not in use, keep center cap of lid closed to prevent moisture loss.

**Select-A-Size:** For a 7"x 8" towel - pull one towel gently through the hole, angle sharply and detach at the first perforation. For a 7" x 16" towel - pull two towels gently straight up through the hole. Hold second towel, angle sharply and detach at the second perforation. NOTE: Select-A-Size feature for the larger size towel works best after several smaller towels have been used.

### Soft pack

Open package. Pull out wipes as needed and reseal. When not in use keep sealed to prevent moisture loss.

## Individually wrapped Pack

Tear open packet. Unfold.

RESEAL HERE

**PULL TAB** 

Remove [flaps] [lid] to create dispenser.

REORDER NO.

See expiration date [on package].

## [This is not a baby wipe] [Not for personal use.]

Pre-moistened disposable towels for use in healthcare and other areas where control of cross contamination is required. Meets OSHA Bloodborne Pathogen Standards. **Surfaces:** For use on hard, non porous surfaces such as stainless steel, glazed ceramic tile, hard plastics, nonporous vinyl, painted surfaces, glazed porcelain, sealed fiberglass surfaces, Plexiglas[®]¹, laminated plastic countertops, and glass. [This product [is] not intended for use on fabrics.]

1Plexiglas is a [registered] trademark of [Arkema, Inc.] [a subsidiary of] [Arkema, Inc.] [or one or more of its affiliates].

### Use Sites [Hospitals, Healthcare, and Home Healthcare]:

Hospital and Healthcare: Clinics, Dental offices, Emergency rooms (ER), Hospitals, Hospital central service areas, Intensive Care Units (ICU), Laboratory, Nursing homes, Physical therapy, Physician offices, Radiology, Recovery rooms and Surgery.

Critical Care Areas: ER, ICU, Neonatal Intensive Care Units (NICU), Pediatric Intensive Care Units (PICU) and Surgery.

**Applications:** Hard, nonporous surfaces such as autoclaves, bed railings, blood glucose monitors, cabinets, carts, chairs, counters, exam tables, gurneys, infant incubators and care cribs, IV poles, phlebotomy trays, plastic mattress covers, PVC tubing, stretchers, tables, ambulance equipment, diagnostic equipment, dialysis machines, mammography equipment, patient monitoring equipment, respiratory equipment, ultrasound transducers and probes, and wheelchairs.

Nursery or Daycare Centers: Changing tables, cribs, trash cans, toys and other hard, nonporous surfaces listed on this label.







Optional graphics. May be placed anywhere on label/container.

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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.

# Dispenser directions:

## Canister directions

To open: Remove lid. Discard inner seal from canister.

To thread: Find center of wipe roll, twist corner of first wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out and tearing off. When not in use, keep center cap of lid closed to prevent moisture loss. Gloves should be worn.

Select-A-Size: For a 7"x 8" towel - pull one towel gently through the hole, angle sharply and detach at the first perforation. For a 7" x 16" towel - pull two towels gently straight up through the hole. Hold second towel, angle sharply and detach at the second perforation. NOTE: Select-A-Size feature for the larger size towel works best after several smaller towels have been used.

### Soft pack direction

Open package. Pull out wipes as needed and reseal. When not in use keep sealed to prevent moisture loss. Gloves should be worn.

# Individually wrapped Pack directions

Tear open packet. Unfold and use as directed. Discard after single use. Gloves should be worn.

**To Clean, Disinfect, and Deodorize in One Step:** Wipe surface with towel until completely wet. Let stand for one minute. To kill TB, let stand for two minutes at room temperature  $(20 - 25^{\circ}\text{C} - \text{or-} 68 - 77^{\circ} \text{ F})$ . Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting. Gloves should be worn.

To Clean: Follow directions above, but no standing time is required. If streaking is observed, wipe with a clean, damp cloth or paper towel.

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7/24/13 5:37 PM

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\*Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile\*## spores. 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 [\*Product Name\*] [this product\*]. 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 Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

**Disinfection Procedure:** Wipe surface with towel until completely wet. Let stand for five minutes. Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting. Gloves must be worn.

Ultrasound transducers and probes: \*\*

R0887059\_clean\_Rosie

For use on external surfaces of ultrasound transducers and probes only.

To disinfect: Pre-clean gel from external surface of ultrasound transducer or probe to be disinfected with a paper towel or clean cloth. Then thoroughly wet the probe with a [**Product Name**] towel. Let stand for one minute. To kill TB, let stand for two minutes at room temperature.

**†KILLS HIV**\*†††, **HBV**\*††† and **HCV**\*††† **ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare 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 Human Immunodeficiency Virus Type 1 (HIV-1)††† (associated with AIDS), Hepatitis B Virus (HBV)†††, and Hepatitis C Virus (HCV)†††. **Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus), HBV and HCV on Surfaces/Objects Soiled with Blood/Body Fluids.** : When handling items soiled with blood/body fluids, personal protective equipment such as disposable gloves, gowns, masks, and eye coverings must be used. **Cleaning Procedure:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before disinfecting. **Contact Time:** Let stand for one minute. **Disposal of Infectious Materials:** Blood, body fluids, and cleaning materials must be autoclaved and disposed according to federal, state, and local regulations for infectious waste disposal.

# NOTE TO REVIEWER: This statement to be used on institutional labels with medical use sites, medical devices and/or bloodborne pathogens:

\*\*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 barrier 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.

tttNote to reviewer: not to be included for "Home Healthcare" product or kit labeling

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## Optional Claims. They may be placed anywhere on label/container.

Now -and/or- New [!] and -or- & Improved [!] to be used as a claim descriptor only for the first 6 months of product on shelf.

- A potable water rinse is required for food contact surfaces.
- · A solution impregnated in a wiping cloth
- An effective method to clean, deodorize and disinfect against odorcausing organisms on hard, nonporous surfaces listed on this label.
- An effective way to disinfect hard, nonporous environmental surfaces listed on this label.
- · Antibacterial formula
- [Appropriate] [Perfect] [Ideal] [for] Terminal Cleaning Patient Discharge[s] [ing]
- Attacks and kills [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\* [spores] [on precleaned, hard, nonporous surfaces] [\*].
- [Bactericidal] [Tuberculocidal] [Virucidal†] [Fungicidal -orantifungal] [Sporicidal] [Disinfectant].
- · Broad Spectrum Disinfectant
- · Cleans, disinfects and deodorizes
- Convenient
- Delivers consistent [amount of solution] concentration every time[!]
- Designed for killing [Clostridium difficile] [C. difficile] [C. diff]
   [(C. diff)]\*## [spores] [\*] [on precleaned, hard, nonporous surfaces] in hospitals.
- · Designed for the Medical/Dental/Health Care industry
- [Designed] [for] [with] [the] Environmental Services Professional[s] [in] [mind] [!]
- [Destroys] [Deactivates] [[Helps] Eliminate] [tough-to-kill] [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \* [spores] [on precleaned hospital surfaces] [\*].
- Disinfectant
- Disinfects hard, nonporous environmental surfaces listed on this label
- Disposable
- Do not use on glassware, utensils or dishes.
- Does not produce mist or overspray
- · Easy and convenient to use
- · Easy to handle
- Effective against [Influenza A H1N1] [H1N1] [insert any organism from the list on page 1] [and] [C. difficile spores] [on precleaned, hard, nonporous surfaces] [\*].
- Effective against [insert any organism from list of organisms] [and] [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)]††† [spores] [on precleaned, hard, nonporous surfaces] [\*].
- Effective against Avian Influenza A and H1N1 [Pandemic] [Influenza A virus].
- [Effective] [For daily use against] [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\* [spores] [on precleaned, hard, nonporous surfaces] [\*].
- [Efficacy tests have demonstrated that [*Product Name*] [this product] [are] [is] an effective bactericide, virucide†, tuberculocide, and fungicide in the presence of organic soil (5% blood serum)]
- · Eliminates airborne particles associated with sprays
- · Eliminates [daily] mixing and measuring
- EVS [Environmental Services]
- [For] general use

- · For use on bathroom surfaces
- · For use on nursery surfaces
- Formulated to kill [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] | the continuous surfaces of the continuous sur
- · Fresh lingering bleach scent
- Fungicidal -or- antifungal
- · [Heavy] cloth-like towel
- Institutional [size]
- Kills [bacteria] [viruses] [fungi] [C. difficile spores] [on precleaned, hard, nonporous surfaces] [\*].
- Kills [bacteria] [viruses] [fungi] [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \* [spores] [\*].
- Kills [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\*tt [spores] in 5 Minutes [\*] [on precleaned, hard, nonporous surfaces].
- Kills [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)]\*\*
  [spores] [\*] [on precleaned, hard, nonporous surfaces] [when used according to instructions].
- [Kills] [Is effective against] 99.9999% of [Clostridium difficile] [C. difficile] \*\*tt\* spores in 5 [minutes] [min] [on precleaned, hard, nonporous surfaces] [\*].
- [Kills] [Is effective against] [99.9999% of] [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] [fff [spores] [in 5 [minutes] [min]] [\*] [on precleaned, hard, nonporous surfaces].
- Kills microbes, including the spore form of [Clostridium difficile]
   [C. difficile] [C. diff] [(C. diff)] the [spores] [\*] [on precleaned, hard, nonporous surfaces].
- Large[r] Surface[s]
- Larger wipe covers [more surface area] [larger area] [with less effort] [!]
- · No measuring
- No mixing
- · Not formulated to contain mercury
- [Passes] [Meets] [Satisfies] [EPA] requirements for killing [Clostridium difficile] [C. difficile] ## spores [on precleaned, hard, nonporous surfaces] [\*].
- Pre-measured
- Premoistened
- · Prevents formulation errors
- [**Product Name**] are intended for cleaning and disinfecting hard, nonporous surfaces where control of cross-contamination is required.
- [*Product Name*] are pre-moistened with a unique, stabilized bleach and detergent solution and are ready-to-use.
- [**Product Name**] are useful in a variety of healthcare and nursery/daycare applications listed on the [this] label.
- [Product Name] may be used to clean and disinfect in one step; see directions for use on this label for cleaning and disinfecting in one step.
- · Ready to U[u]se

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Optional Claims. They may be placed anywhere on label/container. continued

Now -and/or- New [!] and -or- & Improved [!] to be used as a claim descriptor only for the first 6 months of product on shelf.

- Ready-to-use disinfectant [disinfection] for [killing] [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\* [spores] [\*] [on precleaned, hard, nonporous surfaces].
- Renders [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] ###
   [spores] inactive[\*] [on precleaned, hard, nonporous surfaces].
- Respiratory illnesses attributable to Pandemic 2009 H1N1 are
  caused by influenza A virus. [This product] [*Product Name*] is a
  broad-spectrum hard surface disinfectant that has been shown
  to be effective against (influenza A virus tested and listed on the
  label) and is expected to inactivate all influenza A viruses including
  Pandemic 2009 H1N1 (formerly called swine flu).
- · Shelf-stable formula
- [Strong.] [Durable,] cloth-like wipes
- [Strong,] [Durable,] non-woven disposable cloth
- [Strong,] [Durable,] non-woven wipe does not leave lint on surfaces [following use]
- · Suitable for hospital use
- Suitable for use on [titanium-coated] [medical grade] stainless steel
- Suitable for use on hard, nonporous inanimate environmental surfaces
- Suitable for use on insert surface material(s) listed
- [The] smell of clean
- [This product] [*Product Name*] has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

- [This product] [**Product Name**] has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- To break down and kill [inactivate] [help prevent the spread of] [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\* [spores] [on surfaces] [\*] [on precleaned, hard, nonporous surfaces].
- To decontaminate [Clostridium difficile] [C. difficile] [C. diff]
   [(C. diff)]††† [spores] [on precleaned, hard, nonporous] laden surfaces [\*].
- To fight [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] [spores] ## [onprecleaned, hard, nonporous surfaces] [\*].
- To kill [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\*the content of the cont
- To reduce [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\*tt [spores] on [precleaned, hard, nonporous] surfaces in \*\*insert from use sites listed [\*].
- To reduce transmission of [Clostridium difficile] [C. difficile] [C. diff] [(C. diff)] \*\* [spores] [on precleaned, hard, nonporous surfaces] [\*].

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#### Use Sites/Surfaces:

Acute care facilities

Airplanes

Anesthesia Rooms [Areas]

[Assisted Living] [Full Care] Nursing Homes

Bars

Bathroom[s]

[Bed] Head [Foot] Board

Bedroom[s] Blood Banks Bowling Alleys BP Monitors Butcher Shops Cafeterias

CAT Lab[oratories] Central Service Areas

Central Supply [Rooms] [Areas]

Chemotherapy Hoods

Churches Colleges

[Commercial] [Institutional] Kitchens

Correctional Facilities
[Critical Care Units] [CCUs]

Day Care Centers

Delis

Dental Operatories Dialysis Clinics

Dining Hall -or- Room[s]

**Dormitories** 

[Emergency Medical] Transport Vehicles

**Factories** 

Fast Food [Chains] [Restaurants]

Food [Service] [Processing] Establishments

Food Preparation and Processing Areas

Food Serving Areas Footboards

Funeral Homes Grocery Stores

[Gymnasiums] [Gyms]

Headboards

Health Care [Settings] [Facilities]

Health Club Facilities
Home Healthcare [Settings]

[Hospital] Kitchens

Hotels

Industrial Facilities

IV Stands Kitchen[s] Laundromats Laundry Rooms Locker Rooms

Manufacturing (Plants) [Facilities] [Mayo] [Instrument] Stands

[Medical] Clinics Medical Facilities

Military Installations

Motels

Nurse Call Device [and Cord]

Nurse-Call [Device] [Button] [and Cord]

[Nursing] [Nurses'] Stations

Orthopedics

Other Food Service Establishments

Outpatient Clinics Patient Restrooms Patient Rooms

[Pediatric] [Examination Rooms] [Areas]

Pharmacies
Produce Areas
Public Areas

Recreational [Centers] [Facilities]
Respiratory [Therapy Rooms] [Areas]

Restaurants

[Restrooms] [Restroom] Areas

School Buses School Kitchens Schools Shelters Shower Rooms Sill[s] Ledge[s]

Storage [Rooms] [Areas]

Supermarkets

[Surgery Rooms] [Operating Rooms] [ORs]

Trains

[TV] Remote[s] [Control] [s]

Universities

[Bracketed information is optional text.] Green erlined text is new. Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. R0887059 clean Rosie

# Use Sites/Surfaces (continued):

any washable (food and non-food contact)

surface where

disinfection is required appliance exteriors

[bath]tubs

[bathroom] fixtures

bed pans

bed rails/railing

[bedside] commodes -or- tables

bedframes

behind and under counters behind and under sinks

booster chairs cabinet [handle]s

ceilinas closet handles coated mattresses coated pillows [computer] monitors [dental] countertops dental operatory surfaces

[dentist] [dental] chairs desk tops desks

[diaper] [infant] changing tables

diaper pails

dictating equipment [surfaces]

dish racks doorknobs drain boards

[exam] [examination] tables

[exterior surfaces of air vents]

[air vent exteriors]

[exterior] [external] toilet surfaces [exterior] [external] urinal surfaces

[external surfaces of [medical] equipment]

[[medical] equipment

surfaces1

external [surfaces of] ultrasound ...

transducers [\*\*] glucometer exteriors

faucets floors food cases food travs freezers

[garbage] [trash] cans

[grocery store] [supermarket] carts

hampers hand railings

hard, nonporous [environmental] [hospital]

[medical] surfaces

hard, nonporous [environmental] dental

surfaces headsets

high touch surfaces

highchairs hoods

[hospital] [patient] [bed railings] [linings]

[frames]

[inner] [inside of] drawers

lamps

light lens covers

linoleum

med[ication] carts microwave exteriors

other telecommunications equipment

[surfaces]

outdoor furniture (excluding wood frames

and upholstery) oven exteriors patient chairs phone cradle pipes playpens

reception [counters] [desks] [areas]

refrigerator exteriors salad bar sneeze guards

shelves shower walls

[showers] [shower stalls]

sinks stall doors support bars tables [tele]phones [tiled] walls

toilet seats -or- rims towel dispensers [vanity tops] [vanities]

wash basins

Note: Bold, italicized text is information for the reauer and is not part of the label. [Bracketed information is optional text.] Green underlined text is new, Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. R0887059 clean Rosie

EPA Reg. No. 56392-8 Dispatch® Hospital Clea Disinfectant Towels with Bleach Page 10 of 18

### Additional Surfaces:

acrylic glass

[baked] enamel

[common] hard, nonporous [household] [environmental]

surfaces Formica[®]2 glass

glazed ceramic tile hard plastics

laminated surfaces

Marlite[®]3 plastic [laminate] porcelain enamel

stainless steel synthetic marble

vinyl [tile]

<sup>2</sup>Formica is a [registered] trademark of [The Diller Corporation] [a subsidiary of] [Formica] [Formica Corporation] [or one or more of its affiliates].

Marlite is a [registered] trademark of [Marlite, Inc.] [a subsidiary of] [Marlite, Inc.] [or one or more of its affiliates].

Not Recommended For Use On -or- Avoid Contact With:

aluminum

chipped enamel

brass

chrome

clear plastic

clothes

copper fabric

natural marble

painted surfaces paper surfaces

rubber

sealed granite

silver

[unfinished] wood

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EPA Reg. No. 56392-8 Dispatch® Hospital Cleaner
Disinfectant Towels with Bleach
Page 11 of 18

# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs, such as "Germ Disinfection Kit", "Home Care Clean-Up Kit."

### FRONT PANEL

- Kit Name (ABN to be submitted)
- Product Name (ABN to be submitted)
- Signal Word Highest category signal word for the products in the kit on front panel; product specific signal word on back/side panel)
- Referral to Side/Back Panel for Additional Precautionary Statements
- Keep Out of Reach of Children Statement
- · Net Weight/Net Contents

# KEP OUT OF REACH OF CHILDREN CAUTION: SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS. MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS PRECAUCIÓN: VEA EL PANEL POSTERIOR PARA DECLARACIONES PREVENTIVAS ADICIONALES. Si usted no entiende la etiqueta, busque a alquien para que se la explique a usted en detalle.

Kit Contents including, but not limited to, the following:

HAND SANITIZER/DESINFECTANTE PARA MANOS - 2 FL OZ (59 ml) Hon-latex gloves/guantes non-latex - Quantity: 5 pairs/5 pares

ANTIMICROBIAL SOAP/JABÓN ANTIMICROBIÁL - 1.52 FL OZ (45 mL) Disinfecting & Deodorizing Spray/Spray Desinfectante y Desodorante - 5 oz (142 g) Broad Spectrum Disinfecting Bleach Wipes/Paños Desinfectantes con Cloro - 10 ct

## SIDE/BACK PANEL

Product Section:

- Product Name (ABN to be submitted)
- EPA Registration Number
- Ingredient Statement
- Signal Word
- · Precautionary Statements
- First Aid Statements
- Referral to Read the Labels on the Containers in the Kit for Full Directions for Use

# Clorox® CareConcepts Broad Spectrum Disinfecting Bleach Wipes

EPA Reg. No. 56392-8. EPA Est. No. 8251-0H-1.

**ACTIVE INGREDIENT:** 

 Sodium Hypochlorite
 0.65%

 OTHER INGREDIENTS:
 99.35%

 TOTAL:
 100.00%

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See product label for Directions for Use.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. FIRST AID: If in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. If present, remove contact lenses after the first 5 minutes of rinsing, then continue rinsing eye. Call a poison control center or doctor for further treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Poison Control Center: (800) 446-1014. CHEMICAL HAZARDS: Do not use this product with ammonia or acids such as vinegar, rust removers or toilet howl cleaners.

# GENERAL/COMPANY INFORMATION SECTION

- · Name/Address of Producer or Registrant
- EPA Establishment Number

Mfg. for Clorox Professional Products Company, Distributed by The Clorox Company 1221 Broadway, Oakland, CA 94612.

Clorox is a registered trademark of The Clorox Company. CareConcepts is a trademark of The Clorox Company.

@2013 Made in the USA.

EPA Est. No. XXXXX-XX-X (input final facility/co-packer for kit).

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Note: Bold, italicized text is information for the reads, and is not part of the label.

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EPA Reg. No. 56392-8 Dispatch® Hospital Cleaner

Disinfectant Towels with Bleach
Page 12 of 18

# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs such as "Germ Kit" and "Clean-Up Kit."

# KEEP OUT OF REACH OF CHILDREN CAUTION

NOT TO BE USED AS BABY WIPES -orThis is not a baby wipe [Not for personal use.]
KEEP PACKAGE -OR- CONTAINER TIGHTLY SEALED WHEN NOT IN USE
Read Complete Directions and Precautions on Back -or- side -or- rear
[Panel[s]] [Dispenser Carton]
SELECT A SIZE (For Canister Only)

[Net] [Contents] [# of towels and size and weight]

Each package type and size will bear the actual net contents in pounds and ounces

- [Contains 6500 ppm Sodium Hypochlorite]
- [Pre-Moistened Towels with 1:10 Dilution of Bleach [(6.0%)] and Detergent]

Questions or Comments? Call (800) 492-9729 or visit us at www.[insert website].com.

Mfd. for Clorox Professional Products Company, Distributed by The Clorox Company.

1221 Broadway, Oakland, CA 94612.

A list of this product's ingredients is available at www.lngredientsInside.com -or-

A list of [this product's] [product name] ingredients is available at

[insert company website].

Clorox -and/or- CareConcepts is -or- are a registered trademark[s] of The Clorox Company *insert trademark* is a [registered] trademark of The Clorox Company

EPA Reg. No. 56392-8 EPA Est. No. 8251-OH-1 (Q6); 5813-GA-2 (VG); IL-2 (VF)

Beginning of batch code indicates Est. No.

# PRECAUTIONARY STATEMENTS: Hazards to humans and domestic animals. CAUTION:

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

### FIRST AID

If in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. If present, remove contact lenses after the first 5 minutes of rinsing, then continue rinsing eye. Call a poison control center or doctor for further treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [Emergency Information: 1-800-446-1014. -or- Poison Control Center: (800) 446-1014 -or- Clorox Information Line: 1-888-797-7225 -or- Questions? Call 1-888-797-7225.]

## PHYSICAL OR CHEMICAL HAZARDS

Do not use this product with ammonia or acids such as vinegar, rust removers, or toilet bowl cleaners.

### STORAGE AND DISPOSAL:

# For soft packs and individually wrapped packs

Store this product in a cool, dry area away from direct sunlight and heat. Nonrefillable container. Do not reuse or refill this container. Discard used towel and empty package in trash. [Do not flush towels down toilet.]

[Bracketed information is optional text.] Green underlined text is new, Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. R0887059\_clean\_Rosie

EPA Reg. No. 56392-8 Dispatch® Hospital Cleane Disinfectant Towels with Bleach Page 13 of 18

# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs such as "Germ Kit" and "Clean-Up Kit."

# Packaging Related Statements

For fold-pack labels:

Peel for [here] [additional] directions [for use][.]

Soft pack direction

Open package. Pull out wipes as needed and reseal. When not in use keep sealed to prevent moisture loss. Gloves should be worn.

Individually wrapped Pack directions

Tear open packet. Unfold and use as directed. Discard after single use. Gloves should be worn.

RESEAL HERE

**PULL TAB** 

Remove [flaps] [lid] to create dispenser.

Optional graphics. May be placed anywhere on "Home Healthcare" kit carton/labeling, label/container or ABN.



[Not for personal use.]













[[Use your phone to] go here -and/or- scan [[the] tag -or- [this] code] to learn -or- get -or- see [more] uses -orinformation [on how-to-use [This Product]] -or- [how-to] tips -or- [how-to [-use]] videos] [(Data rates may apply)]

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EPA Reg. No. 56392-8 Dispatch® Hospital Cleaner Disinfectant Towels with Bleach Page 14 of 18

# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs such as "Germ Kit" and "Clean-Up Kit."

## **DIRECTIONS FOR USE:**

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

**To Clean, Disinfect, and Deodorize in One Step:** Wipe surface with towel until completely wet. Let stand for one minute. [To kill TB, let stand for two minutes at room temperature  $(20 - 25^{\circ}\text{C} - \text{or-} 68 - 77^{\circ} \text{ F})$ .] Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting. Gloves should be worn.

To Clean: Follow directions above, but no standing time is required. If streaking is observed, wipe with a clean, damp cloth or paper towel,

## To be used for collateral material

- Wipe surface[s] to be disinfected [and deodorized] with [the]
   (insert ABN) -or- this product until completely wet. Let stand
   for one minute. Wipe dry or allow to air dry. Gross soil must be
   removed prior to disinfecting. Gloves should be worn.
- -or
- Wipe surface[s] to be disinfected [and deodorized] with [the] (insert ABN) -or- this product. Refer to [product] label for directions for use and precautionary statements.

## NOTE TO REVIEWER: This statement to be used on labels with medical devices used in home healthcare settings:

\*\*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 barrier 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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[Bracketed information is optional text.] Green underlined text is new, Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. R0887059 clean Rosie

# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs such as "Germ Kit" and "Clean-Up Kit."

The following claims are to be used on the home healthcare labeling. "HomeHealthcare" ABN of this product label and/or the educational kit insert.

The kits will include home healthcare products and educational material such as the following:

hand sanitizers and antimicrobial hand soap; personal protective equipment (i.e. gloves, masks and gowns); other cleaners or antimicrobials; and an educational insert for the products mentioned along with information for proper home healthcare hygiene.

## General/Non-pesticidal Claims

- · Advanced cleaning formula
- · Be ready
- Care -or- caregiving concepts
- · Cleaning made easy
- Clean Home
- Cleaning
- · Cleans the toughest soils
- · Cleans tough messes
- · Clorox® clean
- Contains [Clorox®] bleach
- · Contains no abrasives, harsh acids
- Cuts cleaning time
- · Deep clean[ing] [formula]
- · Delivers a clean you can see and smell
- Designed for Home Healthcare -and/or- patients -and/orcaregivers
- Designed -or- developed for Home Caregivers
- Designed -or- developed for use in Home Healthcare -or- Home
- Designed to be used around -or- for care of -or- in the care of Immune-compromised -or- chemotherapy patients -or- individuals
- Designed to be used around -or- for care of -or- in the care of those with weakened immune systems -or- hospital-acquired infections.
- · Dries quickly
- · Easy to use
- · Effectively removes everyday soils
- · Eliminates odors from fecal matter and urine
- · For a cleaner, fresher household
- For more advice -or- tips -or- education -or- support -orinformation) visit us at www.(insert website).com
- For more advice -or- tips -or- education -or- support -orinformation) call us [toll free] at (insert phone number)
- For more advice -or- tips -or- education -or- support -or- information) visit us at our Facebook page at www.(insert website).com
- For more advice -or- tips -or- education -or- support -orinformation) visit us at www.(insert website).com
- [For] Surface [care]
- [For] Surface cleaning
- For Use by Home Caregivers

- · For Use in Home Healthcare
- [Formulated -or- Designed to] remove[s] biological odors including Urine -and/or- Feces -and/or- Vomit
- Freshens
- · Great for everyday use
- · Great for use around the home
- (Insert product Brand, e.g. Clorox®) is a new line of home caregiving product and practical resources. Kits are available for the most common caregiving needs (as well as refill -and/or-replenishment items.]
- [Kit] Contains care giver protective items [gloves -and/or- masks -and/or- gowns1
- · Leaves a fresh bleach scent
- · Leaves nothing behind
- Lightly scented -or- quick-dissipating scent
- Making home healthcare more manageable -or- easier -or- simpler
- · Maximum cleaning, minimum effort
- Moist wipes
- Multi-purpose
- Multi-surface
- Neutralizes odors [doesn't [iust] mask]
- No harsh chemical odors or fumes.
- · Non-abrasive formula
- Powers through tough messes
- · Removes [tough] stains
- · Starts cleaning on contact
- · Strong cleaning power
- Usable on a variety of soils
- Use of this product does not produce mist in the air.
- · We're there for you
- Works on -or- effective against -or- removes the following stains -and/or- soils:

### Stains/Soils:

| <b>Bodily Fluids</b> | Feces         | matter  | Throw-Up |
|----------------------|---------------|---------|----------|
| Body oils            | Food Stains   | Saliva  | Urine    |
| Common soils         | Grime         | Spit    | Vomit    |
| Dead skin            | Mucus         | Spittle |          |
| Defecation           | Phlegm        | Sputum  |          |
| Fecal matter         | Protein-based | Stool   |          |

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EPA Reg. No. 56392-8 Dispatch® Hospital Cleane Disinfectant Towels with Bleach Page 16 of 18

# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs such as "Germ Kit" and "Clean-Up Kit."

### Use Sites/Surfaces:

[For use on hard, non porous surfaces [such as]]:

acrylic glass

appliance exteriors

bathroom[s]

bed rails/railing

bedroom[s]

[bedside] commodes -or- tables

bedframes:

brush handles

cabinets

canes

cords

countertops crutches

diagnostic equipment

dining room[s]

freezers Formica[®]2

glass

glucometer exteriors

glazed ceramic tile

glazed porcelain

grab bars

hard plastics

home[s]

laminated plastic countertops

light switches living room[s] Marlite[®]3

nonporous vinyl oven exteriors

painted surfaces [plastic] fly swatters

plastic mattress covers

Plexiglas[®]1 portable bathrooms

prescription container exteriors

[PVC] tubes

refrigerator exteriors

remote control exteriors -or- back

(not buttons)

respirator[s] [exteriors]

rocking chairs safety rails

scales

scooters (Avoid plug or charging port) Note to reviewer: "(Avoid plug or charging port)" is not optional text.

sealed fiberglass surfaces

shower fixtures stainless steel stools

stove exteriors -or- stovetop

[tele]phones [tile] walls

toilet seats -or- rims

walkers

Surfaces: For use on hard, non porous surfaces such as stainless steel, glazed ceramic tile, hard plastics, nonporous vinyl, painted surfaces, glazed porcelain, sealed fiberglass surfaces, Plexiglas[®]1, laminated plastic countertops, and glass.

[This product [is] not intended for use on fabrics.]

1Plexiglas is a [registered] trademark of [Arkema, Inc.] [a subsidiary of] [Arkema, Inc.] [or one or more of its affiliates].

<sup>2</sup>Formica is a [registered] trademark of [The Diller Corporation] [a subsidiary of] [Formica] [Formica Corporation] [or one or more of its affiliates].

Marlite is a [registered] trademark of [Marlite, Inc.] [a subsidiary of] [Marlite, Inc.] [or one or more of its affiliates].

Not Recommended For Use On -or- Avoid Contact With:

aluminum

brass

chipped enamel

clear plastic clothes

chrome

copper

fabric natural marble

painted surfaces

paper surfaces

rubber

sealed granite

silver

[unfinished] wood

EPA Reg. No. 56392-8 Dispatch® Hospital Cleaner Disinfectant Towels with Bleach Page 17 of 18

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# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs such as "Germ Kit" and "Clean-Up Kit."

## "Home Healthcare Kit" Claims

The "Home Healthcare Kit" claims are to be used on the home healthcare labeling and/or the educational kit insert.

The kits will include home healthcare products and educational material such as the following:

hand sanitizers and antimicrobial hand soap; personal protective equipment (i.e. gloves, masks and gowns); other cleaners or antimicrobials; and an educational insert for the products mentioned along with information for proper home healthcare hygiene.

# Disinfecting/Pesticidal Claims:

- Antibacterial formula
- [Bactericidal] [Tuberculocidal] [Virucidal††] [Fungicidal -or-antifungal] [Sporicidal] [Disinfectant].
- . Broad Spectrum Disinfectant
- [Cleans [and], Disinfects, [& Deodorizes] in One Step]
- Demonstrated Effectiveness against [:insert organism[s] from page 18] [on hard, nonporous surfaces -or- on (insert use site)]
- Deodorizes
- Disinfectant
- [Efficacy tests have demonstrated that [**Product Name**] [this product] [are] [is] an effective bactericide, virucide††, tuberculocide, and fungicide in the presence of organic soil (5% blood serum)]
- [Efficacy tests have demonstrated that [*Product Name*] [this product] [are] [is] an effective bactericide, virucide††, tuberculocide, and fungicide in the presence of organic soil (5% blood serum)]
- [For] Disinfecting
- [For] Germ Kill
- · Fungicidal -or- antifungal
- Helps prevent patient-to-caregiver and caregiver-to-patient [cross-] spread of germs
- Helps reduce the spread of germs -or- bacteria -or- viruses -orpathogens [on hard, nonporous surfaces.]
- Helps reduce the spread of germs -or- bacteria -or- viruses
   -or- pathogens -or- insert organism[s] from page 18 on hard,
   nonporous surfaces.
- [In circumstances of room contamination,] clean [room] from cleanest to dirtiest surfaces, [and] [Clean] from highest to lowest [surfaces] [using (insert ABN) -or- this product to clean and disinfect high-touch areas]
- (Insert product Brand, e.g. Clorox®) is a new line of products and practical advice, [that includes help with killing germs] [that may be brought home from the hospital or outside], [when you are caring for loved ones at home]. The disinfecting products included [are designed to] kill germs [and prevent the spread of germs] [on hard non-porous surfaces].

- [Kills [99.99% of] bacteria, viruses†† & fungi in 1 Minute on Hard, Nonporous Surfaces]
- Kills [99.9% of] germs [on hard surfaces]
- Kills a broad spectrum of [home] healthcare germs on hard surfaces [in 1 min[ute]] [:insert organisms from page 18]
- Kill[s] -and/or- Fights -and/or- Effective against germs that can cause [home care] infections -or- illnesses [:insert organism[s] from page 18].
- Kill[s] -and/or- Fights -and/or- Effective against [:insert organism[s] from page 18] [on hard, nonporous surfaces -or- on (insert use site)].
- Kills -or- Fights -or- is effective against [:insert organism[s] from page 18] [on hard, nonporous surfaces -or- on (insert use site from page 16)
- Kills Pandemic 2009 H1N1 influenza A virus [(formerly called swine flu)].
- Pay close attention to hot spots or frequently touched surfaces (insert use sites and surfaces) and disinfect regularly, up to 3 times daily
- Prevent[s] the spread of [the most] [common] [home care] germs
   -or- pathogens
- Products -and/or- advice -and/or- care for preventing the spread of common Home HealthCare germs.
- Products and [practical] advice -or- tips for [helping to] prevent[ing] the spread of germs
- Solutions -and/or- disinfection products -and/or- support for- [helping to] prevent[ing] the spread of [the most] [common] home [health] care germs
- Solutions -and/or- disinfection products -and/or- support for [the most] [common] home [health]care germs
- Solutions -and/or- disinfection products -and/or- support for-[helping to]prevent[ing] patient-to-caregiver and caregiver-topatient [cross-]spread of[the most] [common] home [health]care germs

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Note: Bold, italicized text is information for the real... and is not part of the label.

[Bracketed information is optional text.] Green underlined text is new. Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. B0887059 clean Rosie

# Addendum to DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) to Support Home Healthcare Labeling

The addendum to the master label includes the information that will appear on home healthcare labeling. The kits will include home healthcare products such as the following: personal care products (e.g. hand sanitizers and antimicrobial hand soap); caregiver protection (e.g. gloves, masks, and gowns); other cleaners or antimicrobial pesticides. The kits will be marketed for various home healthcare needs such as "Germ Kit" and "Clean-Up Kit."

# Disinfecting/Pesticidal Claims continued:

- Solutions -and/or- disinfection products -and/or- support for homes with high risk of germ spread
- Solutions -and/or- disinfection products -and/or- support for killing germs that can cause [home [health]care] infections -and/orillnesses [:insert organisms from page 18]
- Stopping the spread of germs is a common concern for those caring for an [ill] [or immuno-compromised] individual at home.
   Many ill or aging individuals have weakened immune systems and heightened sensitivity to germ-causing infection. Certain drug treatments, chronic diseases, hospital stays, open wounds, or other conditions may also contribute.
- Use (insert ABN) to clean and disinfect high-touch areas[.]

### "HOME HEALTHCARE KIT":

| Organism   | May cause  |  |
|--|--|--|
| Acinetobacter baumanni   | Acinetobacter infection  |  |
| Enterobacter aerogenes   | Enterobacter infection   |  |
| Enterococcus faecalis  | Enterococcus infection   |  |
| Extended Spectrum Beta-Lactamase (ESBL) producing Escherichia coli     | Food-borne illness -or- gastroenteritis  |  |
| ††Hepatitis A Virus (HAV)  | Food-borne illness -or- gastroenteritis  |  |
| ††Herpes Simplex Virus (HSV-2)   | Herpes Simplex 2 Virus   |  |
| ††Influenza A Virus  | Flu  |  |
| Klebsiella pneumoniae  | Klebsiella infection   |  |
| Methicillin Resistant Staphylococcus aureus (MRSA)                     | MRSA Infection -or- Staph infection -or-<br>Antibiotic-resistant Staph infection |  |
| Multi-drug Resistant [(MDR)] Enterococcus faecium [MDR]                | Enterococcus infection   |  |
| Mycobacterium bovis  | Tuberculosis   |  |
| ††Norovirus  | Norovirus, Food-borne illness -or- gastroenteritis                               |  |
| Pseudomonas aeruginosa   | Pseudomonas infection  |  |
| ††Respiratory syncytial virus (RSV)                                    | Common cold  |  |
| ††Rhinovirus 37  | Common cold  |  |
| ††Rotavirus  | Gastroenteritis  |  |
| Salmonella enterica [tested as Salmonella choleraesuis] [(Salmonella)] | Food-borne illness -or- gastroenteritis  |  |
| Staphylococcus aureus [(Staph)]  | Staph infection  |  |
| Trichophyton mentagrophytes  | Fungal infection, Athlete's Foot   |  |
| Vancomycin resistant Enterococcus faecalis (VRE)                       | Enterococcus infection   |  |