



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Kimberly-Clark Global Sales, LLC
2100 Winchester Road
Neenah, WI 54956

APR - 5 2011

Attention: Sally Hayes
Agency for Kimberly-Clark Global Sales, LLC

Subject: Amendment KIMTECH* One-Step Germicidal Wipe – Eye Protection
Amendment – Post Meeting Decision
EPA Reg. No. 9402-13
Amendment Letter Dated October 21, 2010

On October 22, 2010, the Agency received an application for an amendment, referred to above, requesting that the requirement for eye protection be deleted from the precautionary statement on the basis that the product is a saturated wipe. Thus, accidental splashing into the eye is unlikely. The Agency rejected this request on the basis that, "Agency review does not find this to be a valid reason for removal of the eye protection precautionary statement. While the hazard posed from the saturated cloth wipe might not be as great as that posed by a liquid, saturated wipes may drip and are thought to still pose a hazard. Furthermore, there is still a potential for the user to touch the wipe and then rub their eyes."

On February 23, Julie Ownbey from Kimberly-Clark and Sally Hayes from Scientific & Regulatory Consultants, Inc., met with the Agency to discuss the request. Kimberly-Clark raised concerns about an uneven playing field as the Antimicrobial Division has previously advised registrants to remove eyewear protection from towelette labels.

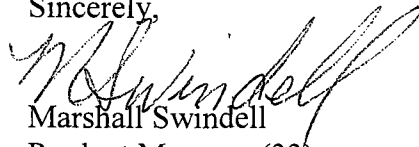
The Agency acknowledges that this is an issue requiring Agency attention. However, in respect of a level playing field, the Agency will not require protective eyewear labeling for this product at this time.

A draft policy on antimicrobial towelettes and wipes is under consideration by the Antimicrobial Division. Once the policy has been finalized, the agency will inform registrants if there are changes that need to be made regarding registration and if there are additional data that must be submitted.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510P)

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{FRONT PANEL}

KIMTECH* [Brand]¹ One-Step Germicidal Wipe
~~Sporicidal[§], Tuberculocidal, Virucidal[†], Fungicidal, Bactericidal~~

ACTIVE INGREDIENTS:

Hydrogen Peroxide 4.40%
Peroxyacetic Acid 0.23%

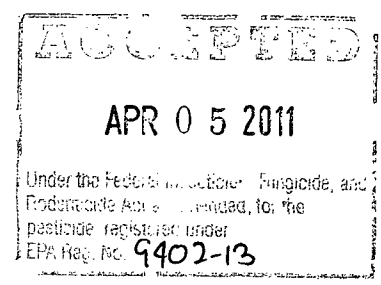
INERT INGREDIENTS: 95.37%

TOTAL INGREDIENTS 100.00%

Keep Out Of Reach Of Children

DANGER

See back panel for additional precautionary and first aid statements



NET WT 24.7oz. (700grams) {Number may change prior to commercialization}
NET CONTENTS 60 {Number may change prior to commercialization}
Pre-[Moistened][Saturated] Wipes 8" [in] x 12" [in] [(20 x 30 cm)] {Number may change prior to commercialization}

E.P.A. Reg. No. 9402-13 {Registration number will appear on printed label}
E.P.A. Est. No. 9402-TX-001 {EPA Establishment number will appear on printed label}

[§]Pre-cleaning required. See back panel.

¹ May be alternately marketed under the brand names "Kimberly-Clark [Brand] One-Step Germicidal Wipe" or "Kimberly-Clark Professional [Brand] One-Step Germicidal Wipe"

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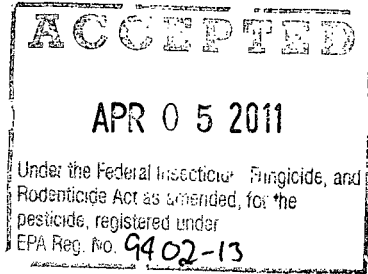
KIMTECH* [Brand] One-Step Germicidal Wipe[s] kill[s] these organisms at the following contact times:

DISINFECTANT

6 [minutes] [mins]	Spores	Viruses
	Clostridium difficile	Norovirus† Poliovirus [Type 1 (Chat)]† Rhinovirus [37]†

1 [minute] [min]	Fungi	Mycobacteria
	Aspergillusniger Trichophytonmentagrophytes	Mycobacterium bovis BCG

30 [seconds] [sec]	Bacteria/Yeast	Viruses
	Acinetobacterbaumannii Candida albicans Escherichia coli O157:H7 Extended Spectrum Beta-Lactamase Escherichia coli [(]ESBL[)] VancomycinResistant Enterococcus faecalis[(]VRE[)] Klebsiellapneumoniae Legionella pneumophila Listeria monocytogenes Pseudomonas aeruginosa Staphylococcus aureus Methicillin Resistant Staphylococcus aureus[(]MRSA[)] Community-AcquiredMethicillinResistant Staphylococcus aureus [(]CA-MRSA[)] (USA 400) VancomycinResistant Staphylococcus aureus[(]VRSA[)] Salmonella enterica Serratiamarcescens Shigellasonnei Penicillin ResistantStreptococcus pneumoniae[(]PRSP[)]	Adenovirus Type 2† Avian Influenza Virus H5N1† Coronavirus (SARS)† Hepatitis B Virus (HBV)† Hepatitis C Virus (HCV)† Herpes Simplex Virus, Type 1† Herpes Simplex Virus, Type 2† HIV-1 (AIDS Virus)† Influenza A Virus [HongKong][HK][H3N2]† [Pandemic 2009] Influenza A Virus H1N1† Rotavirus† Respiratory Syncytial Virus†



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DISPENSING DIRECTIONS:

To open: Remove lid by twisting counter-clockwise and pulling up. [Discard inner seal from canister.] [Replace lid firmly.] [Close lid tightly].

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 1" of wipe through the hole. [Replace lid firmly.][Close lid tightly] [by twisting clockwise to lock lid into position].

To Dispense: Dispense by pulling wipe through the dispensing port. Dispenses one wipe at a time. [Remaining wipes automatically feed through for next use.] Close [top] [lid] tightly [when finished] [to prevent moisture loss].

{optional language for rigid top flexible flat pack/or rigid top tub}: Open top. Remove needed wipes. Close top when finished [to prevent moisture loss].

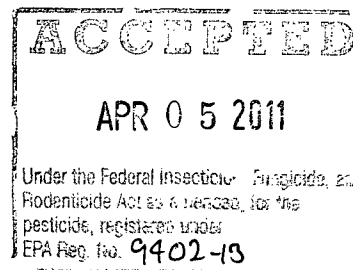
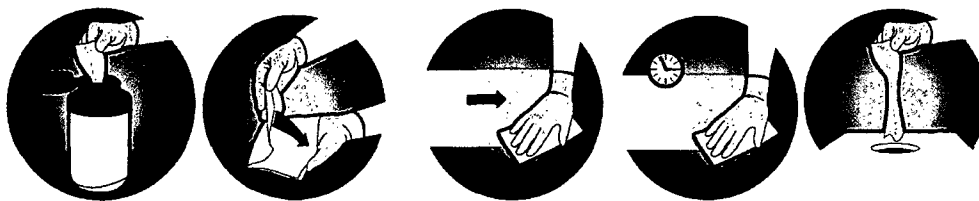
{optional language for peel-back flexible flat pack}: Carefully pull back seal. Remove needed wipes. Reseal when finished [to prevent moisture loss].

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: For nonfood contact surfaces only.

First, use a KIMTECH* [Brand] One-Step Germicidal Wipe to remove heavy soil if present, or if disinfecting against C. difficile spores. Then, use a new, clean wipe to disinfect. Fold wipe [in half] to form a palm-sized [4" x 6"] pad. Thoroughly wipe area to be disinfected at room temperature [(20-24°C)]. Work from clean sections to dirty sections, refolding wipe periodically to expose a clean wipe surface. [Treated area must remain visibly wet for a minimum of 6 minutes for sporicidal activity and non-enveloped viruses, 60 seconds for tuberculocidal and fungicidal activity, and 30 seconds for bactericidal activity and enveloped viruses.] [Refer to chart for effective kill time of target organisms. Wipe target area enough to remain visibly wet for the specified kill time.] Let air dry. [No rinsing required.] Do not reuse [or rewet] dried out wipes. For TB, use a contact time of 1 minute at 20-24°C.

{The following graphics illustrating use directions may be included on the label}



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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 blood stream 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][critical or semi-critical surface]. [For use on non-critical surfaces only]. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

[^(S)For C. difficileSporicidal Disinfection:]

- **Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks [or][and] 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 disinfectant 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.

ACCEPTED

APR 05 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 9402-13

{optionaladditional directions for use}

Ultrasound transducers and probes:

For use on external surfaces of ultrasound transducers and probes only. Pre-clean gel from external surface of ultrasound transducer or probe to be disinfected with a clean washcloth. Wipe probe with KIMTECH* [Brand] One-Step Germicidal Wipe. Treated areas must remain visibly wet for a minimum of 6 min. Let air dry [No rinsing required.] Do not reuse dried out wipes.

[Specific Instructions for Blood Borne Pathogens:] KILLS HIV-1, HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/object 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, and Hepatitis C Virus.

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SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS Virus), [HEPATITIS B VIRUS] HBV and [HEPATITIS C VIRUS] HCV OF SURFACE/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: {select one of the statements}[Clean up should always be done wearing protective gloves, gowns, masks and eye protection.] [Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination.]

Cleaning Procedure: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of this product.

Contact Time: {select one of the first two statements} [Allow surface to remain wet for 30 seconds to kill HIV-1, HBV and HCV.] [Leave surface wet for 30 seconds to kill HIV-1, HBV and HCV.] Use contact times listed for all other organisms claimed.{or}[Consult Chart for all other contact times.]

ACCEPTED
APR 05 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 9402-13

Disposal of Infectious Material: Blood/body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

Areas of Use:

[Disinfectant for use on hard, non-porous surfaces in:]{sites will be selected from the following} Animal Life Science Laboratories, Bathrooms, Churches, Cleanrooms, Clinics, Colleges, Cosmetic Processing Facilities, Critical Care Units, Cruise Ships, Dialysis Centers, Funeral Homes, Dental Offices, Health Clubs, Hospices, Hospitality Establishments, Hospitals, Home Health Care, Hotels, Industrial Facilities, Institutions, Laboratories, Nail Salons, Nursing Homes, Medical Device Manufacturing, Morgues, Office Buildings, Outpatient Centers, Pharmaceutical Production Facilities, Pharmacies, Physical Therapy, Physicians Offices, Public Facilities, Radiology, Recreational Facilities, Rehabilitation Centers, Research Laboratories, Retail and Wholesale Establishments, Shelters, Storage Areas, Surgery Centers, Locker Rooms, Long-Term Care Facilities, The interior areas of the following Transport Vehicles: including ships, airplanes, automobiles, trucks, ambulances, and trains

[Critical Care Areas]: {sites will be selected from the following}CCU, Emergency Rooms, ICU, Neonatal Intensive Care Units (NICU), Operating Rooms, Pediatric Intensive Care Units (PICU), [and] Surgery.

[Use Sites]: [May be used on hard non-porous surfaces of] {surfaces will be selected from the following}autoclaves, bed railings, blood glucose monitors, cabinets, carts, chairs, closets, counters, countertops, desks,exam tables, furniture, garbage cans, gurneys, isolettes,

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infant incubators and care cribs, IV poles, phlebotomy trays, PVC tubing, recycling bins, stethoscopes, stretchers, tables, bathrooms, sinks, faucets, toilet seats [and rims], towel dispensers, hand railings, lamps, light switch panels, stall doors, bath tubs, showers, hampers, tiled walls, telephones, door knobs, vanities, non-porous shelves, display cases, walls, [and] work surfaces.

Hard non-porous external surfaces of: {surfaces will be selected from the following} ambulance equipment, diagnostic equipment, dialysis machines, mammography equipment, patient monitoring equipment, respiratory equipment, ultrasound transducers and probes, [and] patient support and delivery equipment.

KIMTECH* [Brand] One-Step Germicidal Wipe [is compatible with] [will not harm] (surfaces will be selected from the following) aluminum, [Low-Density Polyethylene][LDPE], vinyl, painted surfaces, polypropylene, polyurethane varnish, [Polyvinyl Chloride][PVC], silicone rubber, stainless steel, medical tubing, vinyl rubber, acrylic, brass, [Liquid Crystal Display][LCD] screens, copper, Corian®, glass, laminate flooring and countertops, nickel, polycarbonate, glazed porcelain, zinc alloy.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Causes irreversible eye damage. Do not get in eyes or on 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. Use of gloves is recommended.

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.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

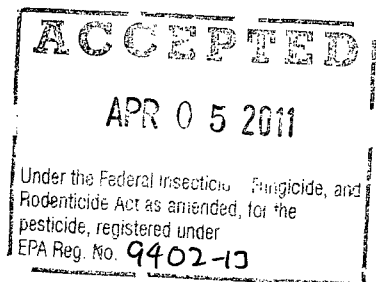
Probable mucosal damage may contraindicate the use of gastric lavage.

Physical and Chemical Hazards

This product contains an oxidizing agent.

Storage and Disposal

Storage: {select at least one of the following statements}[Store [at room temperature] [between 20 – 25 [degrees][°] Celsius] [68 – 77 [degrees][°] Fahrenheit].] [Do not store near heat



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or open flame.] [Store this product in a cool, dry area away from direct sunlight and heat.] [Store in original container in areas inaccessible to children.] [When not in use keep center cap of lid closed to prevent moisture loss.]

Disposal: Wipe: [Do not reuse wipe.] [Dispose of] [Discard] used wipe in trash. [DO NOT FLUSH.] Dispenser: [If empty:] Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available. [If partly filled: Call your local solid waste agency for disposal instructions.] [Discard used towels and container in trash or take container to recycling center.]

Distributed by Kimberly-Clark Global Sales, LLC., 2100 Winchester Road, Neenah WI 54956

For questions/comments, please contact Kimberly-Clark Professional
1400 Holcomb Bridge Road
Roswell GA 30076
1-888-346-4652

www.kcprofessional.com

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™ Trademark of CET, LLC

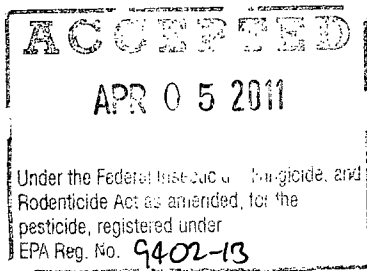
78150{Stock code will appear on label. Number may change prior to commercialization}

Made in USA

Made with PeridoxRTU™ [Disinfectant] [Technology]

{internal specification numbers may also appear on label}

{Lot code and expiration date may appear on either the container or label}



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{Sporicidal claims}

Helps reduce [C. diff] [C. difficile] [Clostridium difficile] [spores] [MRSA] [occurrence]!

Kills 99.9999% [C.diff] [C. difficile] [Clostridium difficile] [spores] in 6 [minutes] [min]!

Kills [bacteria] [fungi] [mold] [TB] [viruses†] on surfaces.

Kills [bacteria] [fungi] [Clostridium difficile] spores [viruses†]

Kills [C.diff] [C. difficile] [Clostridium difficile] [spores] in 6 [minutes] [min]!

Sporicidal⁵, Virucidal†, Bactericidal, Fungicidal, and Tuberculocidal

[Wipe out] [Kill] [Eliminate] [C. diff] [C. difficile] [Clostridium difficile] [spores] [MRSA]

{Influenza A H1N1 Claims}

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. [This product] [KIMTECH* [Brand] One-Step Germicidal Wipe] is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza A Virus [Hong Kong][HK][H3N2] and Avian Influenza Virus [H5N1] and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

This product [KIMTECH* [Brand] One-Step Germicidal Wipe] 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 [KIMTECH* [Brand] One-Step Germicidal Wipe] has demonstrated effectiveness against Influenza A Virus [Hong Kong][HK][H3N2] and Avian Influenza Virus [H5N1] and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

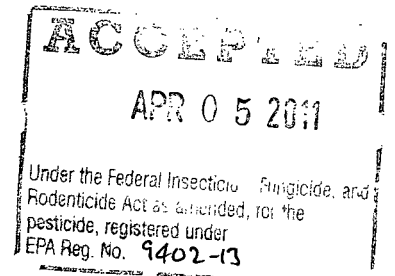
Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus.

{General efficacy claims}

Can help reduce the risk of cross contamination on treated surfaces

[Cleans], [Disinfects] and [Deodorizes]



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Fastkill times!^[2]

Fast kill time[s]!^[1]

Kills [CA-] [Community Acquired MRSA] [and] MRSA in 30 seconds!

KIMTECH* [Brand] One-Step Germicidal Wipe is effective against the following organisms at the following contact times: {insert organism name and contact time from table}

Disinfects in [just] [6] [1] minute(s)

Disinfects external surface of ultrasound transducers

Disinfects hard non-porous [environmental] surfaces listed on this label

Kills {insert organism name from Table} in just {insert contact time from table}

Powerful enough to disinfect

[Product Name] [are] [is] intended for [cleaning] [and] [disinfecting] hard non-porous surfaces where control of cross contamination is required.

{Ease of use}

After use, just toss wipe(s) away

Always ready to use

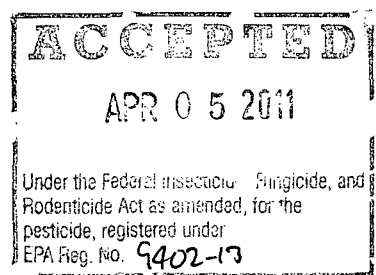
An effective method to deodorize and disinfect against odor-causing organisms on hard non-porous surfaces [listed on this label]

An effective way to disinfect hard, non-porous environmental surfaces [listed on this label]

Cleans and disinfects in one step.

Dispenses one wipe at a time

Does not produce mist or spray



² This claim refers to disinfection data.

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[Convenient] [Portable] way to disinfect hard non-porous surfaces

~~[KIMTECH*-[Brand]-One-Step-Germicidal-Wipe]~~ may be used to clean and disinfect in one step; [see directions for use on this label for cleaning and disinfecting in one step].

[[No mess], [No Dilution], [No rinse], [No dirty rags]]

No [mixing], [measuring] or [rinsing] required.

No sponges, no rags, no buckets, no mess

No rinsing required.

One-Step Presaturated Germicidal Wipe

Premoistened[!]

[KIMTECH* One-Step Germicidal Wipe][sare] [is] pre-moistened with a unique, stabilized Hydrogen Peroxide Peroxyacetic Acid solution and [are][is] ready-to-use.

Easy way to disinfect hard, nonporous surfaces

Easy way to clean [and disinfect] bathrooms

Ready to Use[!]

Simple and easy to use

The [easy], [effective], and [convenient] way to disinfect surfaces.

Use of this product does not produce mist in the air

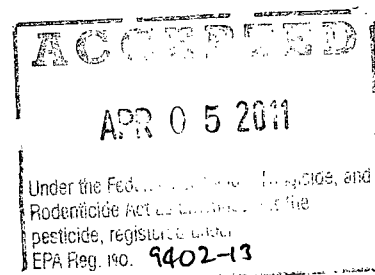
{General claims}

Alcohol Free!

[Big] Sheet Size _" x _"

__% bigger [wipes] [vs. _" x _" wipes]

Bleach-free [formula]



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Bonus

Convenient

Does not contain alcohol.

Does not contain bleach

ErgoCan*

For daily use

Get a fresh, clean [KIMTECH*[Brand] [One-Step Germicidal]] Wipe every time.

KIMClutch*

KIMKlutch*

EZ-GRAB*

GRIPPER*

KIMTECH* Brand

New! {used for 6 months only}

[New {used for 6 months only}] One-Step Germicidal Wipe

Non-corrosive.

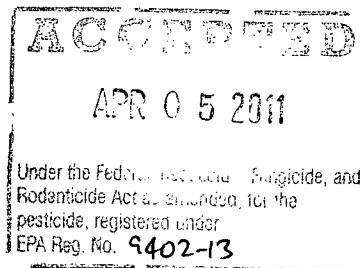
Dispenses one [Wet] Wipe!

Pop-up dispensing

Pop-up [top]

__# Presaturated [towelettes] [wipes] _" x _"

RiteSize*[Twist 'n Lock] [TwistLock] [Twist & Lock] lid [allows easy loading of wipes] [allows effortless access to wipes] [protects fingernails]



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Unique lid design for one-hand [carrying] [transport].

[Use to] Deodorize hard non-porous surfaces

_" x _" [wipes]

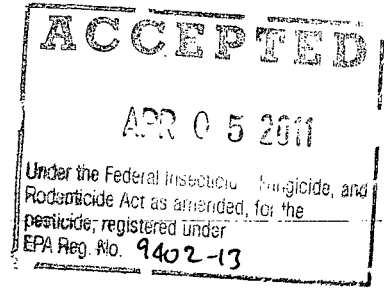
Improved {used for 6 months only}{descriptor to be inserted} [fragrance] [smell]

New {used for 6 months only}{descriptor to be inserted} [fragrance] [smell]

Not a baby wipe.

Graphics

{may be selected from the following, or similar graphics may be used}



PeridoxRTU™ Disinfectant Logo	
KIMTECH* Brand Logo	
Kimberly-Clark Professional Logo	
Kimberly-Clark Logo	
No-Baby Graphic	
Wipe Use Graphic	
Storage Temperature Graphic	

15/15

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{Based on recent comments from J. Harrigan-Farrelly regarding the need for improved labeling and reduced redundancy on labels, we offer the following combined directions for use for blood borne pathogens and Clostridium difficile spores. We propose that this language may be optionally used in place of the 2 separate required statements for each type of organism.}

[^(S)Instructions for Blood Borne Pathogens and C. difficile:] KILLS HIV-1, HEPATITIS B VIRUS (HBV), HEPATITIS C VIRUS (HCV) and CLOSTRIDIUM [C.]DIFFICILE SPORES ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS in health care and other settings in which there is potential for soiling of inanimate surfaces with blood/body fluids or fecal matter/waste which may be associated with transmission of HIV-1, HBV, HCV, or C. difficile.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION:

- **Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks and eye protection. [Wear disposable latex or vinyl gloves, gowns, face masks, or eye coverings, as appropriate, during all cleaning of body fluids, blood, and decontamination.]
- **Cleaning Procedure:** Thoroughly clean blood/body fluids or fecal matter/waste from surfaces/objects before disinfection. Cleaning includes vigorous wiping and/or scrubbing, until all visible soil is removed. High-touch surfaces need special attention. Clean surfaces in patient rooms 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/viruses. Clean restrooms last. Do not reuse soiled cloths.
- **Contact Time:** Allow surface to remain wet for:
 - 30 seconds to kill HIV-1, HBV and HCV and
 - 6 minutes to kill C. difficile spores.

[Leave surface wet for 30 seconds to kill HIV-1, HBV and HCV and for 6 minutes to kill C. difficile spores.] Use contact times listed for all other organisms claimed. [Consult Chart for all other contact times.]

- **Disposal of Infectious Material:** Autoclave blood/body fluids/waste/cleaning materials contaminated with waste and dispose of according to Federal, State, and local regulations for infectious waste disposal. [Immediately dispose of cleaning materials that may contain feces/wastes in accordance with local regulations for infectious materials disposal.]

ACCEPTED

APR 05 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 9402-13