

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 18, 2021

Amanda Burwell Regulatory Specialist 22 West Frontage Road Northfield, Illinois 60093

Subject: PRIA Label Amendment – Addition of 3 organisms to the public health claims in support of SARS-CoV-2 claims Product Name: SCTB Wipe EPA Registration Number: 1839-223 Application Date: October 6, 2020 Action Case Number/Decision Number: 566843

Dear Ms. Burwell:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are

subject to the following additional terms of registration:

- 1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease

outbreak that meets all the following criteria:

a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:

- A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
- B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
- C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (<u>www.cdc.gov/hai/outbreaks</u>)

ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (<u>www.oie.int/wahis\_2/public/wahid.php/Diseaseinformation/WI</u>).

A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroups are large non-enveloped, enveloped.

B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.
- 5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus, ATCC VR-782 (surrogate for Norovirus) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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 section2(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

Page 3 of 3 EPA Reg. No. 1839-223 Action Case Number/Decision No. 566843

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.

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 John Hebert via email at Hebert.John@epa.gov.

Sincerely,

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John Hebert, Chief Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

# **SCTB Wipe**

#### **ACTIVE INGREDIENTS**

Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
dimethyl benzyl ammonium chlorides	0.105%
Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl	
ethylbenzyl ammonium chlorides	0.105%
INERT INGREDIENTS	
Total	100.000%



Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1839-223

# KEEP OUT OF REACH OF CHILDREN

See side (back) panels for additional precautionary statements.

EPA REG. NO. 1839-223 EPA EST. NO. (as indicated on container)

#### **STEPAN COMPANY**

22 W. Frontage Rd. Northfield, IL 60093

NET CONTENTS: X lbs. X ozs. (mandatory: must be expressed in avoirdupois pounds and ounces)

(optional: can also express as total count and size) X Pre-measured (Pre-moistened) (Wipes) (Towelettes) (Cloths) (X)" x (X)" (e.g. 40 Pre-measured Wipes (7" x 8") (18cm x 20cm)

X Pre-measured Single Use (Pre-Moistened) (Wipes) (Towelettes) (Cloths) (X)<sup>°</sup> x (X)<sup>°</sup> (e.g. 40 Pre-measured Towelettes (7<sup>°</sup> x 8<sup>°</sup>) (18cm x 20cm)

#### U.S. Patent No. 5,444,094

(This product or product name) is bactericidal in the presence of organic soil (5% blood serum) against *Escherichia coli (E. coli)* ATCC 11229, *Escherichia coli* O157:H7 ATCC 43895, *Salmonella (choleraesuis) enterica* ATCC 10708, *Pseudomonas aeruginosa* ATCC 15442, Vancomycin Resistant *Enterococcus faecalis* (VRE) ATCC 51575, *Staphylococcus aureus* ATCC 6538 and Methicillin Resistant *Staphylococcus aureus* (MRSA) ATCC 33593 at 5 minutes contact time.

(This product or product name) is bactericidal in the presence of organic soil (5% blood serum) against *Escherichia coli* (*E. coli*) (ATCC 11229), *Escherichia coli* O157:H7 (ATCC 43895), *Salmonella* (choleraesuis) enterica (ATCC 10708), *Pseudomonas aeruginosa* (ATCC 15442), Vancomycin Resistant *Enterococcus faecalis* (VRE) (ATCC 51575), *Staphylococcus aureus* (ATCC 6538) and Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33593) at 5 minutes contact time.

(This product or product name) is tuberculocidal in the presence of organic soil (5% blood serum) against *Mycobacterium bovis* BCG (Tuberculosis) at 20°C at 5 minutes contact time.

(This product or product name) is virucidal\* in the presence of organic soil (5% blood serum) against Human Immunodeficiency Virus Type 1, Strain HTLV-III<sub>B</sub> (HIV-1) (associated with AIDS) at 2 minutes contact time, Influenza A (H1N1) Virus (ATCC VR-1469, Strain A/PR/8/34), Hepatitis B Virus (HBV), Duck Hepatitis B Virus (DHBV), Hepatitis C Virus (HCV) and Bovine Viral Diarrhea Virus (BVDV) at 5 minutes contact time, and **Norovirus (Norwalk Virus), Feline calicivirus, (SARS-CoV-2) (SARS -Related Coronavirus 2) (USA-WA1/2020) (BEI NR-52281)**.

(This product or product name) are (is a) non-woven, disposable (towelette(s)) (wipe(s)), pre-saturated with a quaternary disinfectant cleaner.

(This product or product name) are (is) intended for use in:

 hospitals and healthcare settings: ambulances, anesthesia areas, CAT labs, CCU, Central Supply areas, Clinics, Dental Offices, Dialysis Clinics, Doctor's office(s), Emergency Rooms, E.R., Home health care, Hospices, ICU, Laboratory, Laundry rooms, Neonatal Intensive Care Units (NICU), Newborn nursery, Nursing homes, Operating rooms, Pediatrics facilities, Pediatric Intensive Care Units (PICU), Physical therapy facilities, Physician's office(s), Opthalmic offices, Radiology areas, Recovery Room, Rehabilitation facilities, Respiratory therapy areas, Surgery facilities, Transport vehicles, X-Ray facilities

(and/or)

- Critical Care Areas: CCU, Emergency Rooms, E.R., I.C.U. Neonatal Intensive Care Units (NICU), Operating Rooms, Pediatric Intensive care Units (PICU), Surgery Units, Opthalmic offices
- Veterinary clinics, animal hospitals, animal life science laboratories, kennels, pet animal kennels, breeding establishments, grooming establishments, pet animal quarters, zoos, pet shops, tack shops
- Animal holding areas, veterinary waiting rooms, veterinary examination rooms, veterinary X-ray rooms, veterinary operating rooms, animal transportation vehicles
- Beauty salons, barber shops, correctional facilities, funeral homes, mortuaries
- Schools, health clubs, gyms, athletic facilities, airports, transportation terminals
- Grocery stores, Shopping Centers, Delicatessens, Catering facilities, Banquet halls
- Nursery, Daycare centers

(This product or product name) will clean and disinfect<sup>^</sup> hard, non-porous, surfaces of: bed railings, cabinets, carts, chairs, counters, exam tables, gurneys, isolettes, IV poles, stethoscopes, stretchers, tables, telephones, toilet seats, external toilet surfaces, bathtubs, bathroom fixtures, shower stalls, sinks, tiles, vanity tops, hospital beds, traction devices, MRI equipment, CAT imaging equipment, scales, paddles, wheelchairs, ultrasound transducers and probes.

(This product or product name) will clean and disinfect^ hard, non-porous surfaces of: grocery cart handles, grocery carts, shopping carts, grocery cart child seats.

(This product or product name) will clean and disinfect<sup>^</sup> hard, non-porous surfaces of: changing tables, cribs, diaper pails, trashcans, garbage cans.

(This product or product name) will clean and disinfect<sup>A</sup> hard, non-porous surfaces of: cabinets, chairs, computers, countertops, desks, desktops, doorknobs, fax machines, garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, trashcans.

(This product or product name) will clean and disinfect<sup>^</sup> hard, non-porous surfaces of: gym equipment, exercise machines, wrestling mats, gymnastic equipment.

Use (this product or product name) to clean and disinfect^ non-porous personal protective safety equipment, protective headgear, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, silicone rubber or PVC hearing protectors and vinyl covered ear muffs. Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water (about 120°F), and allow to air dry. (Caution: Cleaning at the 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.)

(This product or product name) is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, non-polycarbonate plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets.

- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) the virus that causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) the Coronavirus that causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces (in) (just)(10 minutes)(!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) SARS-CoV-2 (the coronavirus that causes COVID-19) on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) SARS-CoV-2, which causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) SARS-Related Coronavirus 2 (SARS-CoV-2) (USA-WA1/2020) (causative agent of COVID-19) (the virus that causes COVID-19) on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>A</sup>) (of) (has demonstrated effectiveness against) SARS-CoV-2 virus (responsible for COVID-19 illness) (responsible for COVID-19) on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%<sup>^</sup>) (of) the virus that causes COVID-19<sup>\*\*</sup> (in) (just) (One Step<sup>^#</sup>)
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%<sup>^</sup>) (of) the Coronavirus that causes COVID-19<sup>\*\*</sup> (in) (just) (One Step<sup>\*#</sup>)
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%<sup>^</sup>) (of) SARS-CoV-2 (the Coronavirus that causes COVID-19) (in) (just) (One Step<sup>^#</sup>)
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%<sup>^</sup>) (of) SARS-CoV-2, which causes COVID-19<sup>\*\*</sup> (in) (just) (One Step<sup>\*\*</sup>)
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%<sup>^</sup>) (of) SARS-Related Coronavirus 2 (SARS-CoV-2) (USA-WA1/2020) (causative agent of COVID-19) (the virus that causes COVID-19) (in) (just) (One Step<sup>\*#</sup>)
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%<sup>^</sup>) (of) SARS-CoV-2 virus responsible for COVID-19 (in) (just) (One Step<sup>\*#</sup>)

- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) the virus that causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%^) (of) (has demonstrated effectiveness against) the Coronavirus that causes COVID-19\*\* on hard non-porous surfaces
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%^) (of) (has demonstrated effectiveness against) SARS-CoV-2 (the Coronavirus that causes COVID-19) on hard non-porous surfaces
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) SARS-CoV-2, which causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) SARS-Related Coronavirus 2 (SARS-CoV-2) (USA-WA1/2020) (causative agent of COVID-19) (the virus that causes COVID-19<sup>\*\*</sup>) on hard non-porous surfaces
- This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%<sup>^</sup>) (of) (has demonstrated effectiveness against) SARS-CoV-2 virus (responsible for COVID-19) on hard non-porous surfaces
- (This Product) (Product Name) Kills (99.9%<sup>^</sup> of) SARS-CoV-2, which causes COVID-19\*\* on hard non-porous surfaces
- (This Product) (Product Name) Kills (99.9%<sup>^</sup> of) SARS-CoV-2, which causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces (in) (just) (10 minutes) (!)
- This Product) (Product Name) Kills (99.9%<sup>^</sup> of) SARS-CoV-2, which causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces (in) (just) (One Step<sup>^#</sup>)
- This Product) (Product Name) Kills (99.9%<sup>^</sup> of) SARS-CoV-2, which causes COVID-19<sup>\*\*</sup> on hard non-porous surfaces
- (This Product) (Product Name) Kills (is) (Effective against) the virus that causes COVID-19\*\* on hard nonporous surfaces
- (This Product) (Product Name) Kills (is) (Effective against) the virus that causes COVID-19\*\* on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) Kills (is) (Effective against) the virus that causes COVID-19\*\* on hard non-porous surfaces (in) (just) (One Step^#)
- (This Product) (Product Name) Kills (is) (Effective against) the virus that causes COVID-19\*\* on hard nonporous surfaces
- (This Product) (Product Name) Kills SARS-CoV-2 (COVID 19 virus) (virus) on hard non-porous surfaces
- (This Product) (Product Name) Kills SARS-CoV-2 (COVID 19 virus) (virus) on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) Kills SARS-CoV-2 (COVID 19 virus) (virus) on hard non-porous surfaces (in) (just) (One Step<sup>^#</sup>)
- (This Product) (Product Name) Kills SARS-CoV-2 (COVID 19 virus) (virus) on hard non-porous surfaces
- (This Product) (Product Name) (is) Effective against 2019 SARS-CoV-2 (COVID 19 virus) on hard non-porous surfaces
- (This Product) (Product Name) (is) Effective against 2019 SARS-CoV-2 (COVID 19 virus) on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) (is) Effective against 2019 SARS-CoV-2 (COVID 19 virus) on hard non-porous surfaces (in) (just) (One Step<sup>^#</sup>)
- (This Product) (Product Name) (is) Effective against 2019 SARS-CoV-2 (COVID 19 virus) on hard non-porous surfaces
- (This product) (Product Name) is a broad-spectrum, hard non-porous surface disinfectant that has been shown to be effective against SARS-CoV-2 (COVID-19 virus tested and listed on the label)

#### Claim Qualifier: <sup>^</sup>when used according to disinfection directions Claim Qualifier: \*\*SARS-Related Coronavirus 2

## Claim Qualifier: \*Non-food contact surfaces only(, food contact surfaces require potable water rinse)

#### DIRECTIONS FOR USE

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

(For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used:) 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. *or* 

This product is not for use on critical and semi-critical medical device surfaces.

**CLEANING/DEODORIZING:** Use one (product name) (wipe) (towelette) to deodorize and completely remove all gross debris from surfaces to be treated.

**DISINFECTING:** [(For visibly soiled surfaces, clean before following disinfecting instructions.) (Remove visible soil prior to application of the product.)] To disinfect hard, non-porous surfaces, thoroughly wet the surface to be treated. Treated surface must remain visibly wet for 5 minutes for disinfection:

- To disinfect against *Escherichia coli (E. coli), Esherichia coli* O157:H7, *Pseudomonas aeruginosa, Salmonella (choleraesuis) enterica* and Vancomycin Resistant *Enterococcus faecalis* (VRE), allow the treated surface to remain wet for 5 minutes.
- To disinfect against *Mycobacterium bovis* BCG (Tuberculosis), allow the treated surface to remain wet for 5 minutes.
- To disinfect against *Staphylococcus aureus* and Methicillin Resistant *Staphylococcus aureus* (MRSA), allow the treated surface to remain wet for 5 minutes.

A potable water rinse is required for surfaces in direct contact with food.

#### For plastic and painted surfaces, spot test on an inconspicuous area before use.

**\*VIRUCIDAL ACTIVITY:** [(For visibly soiled surfaces, clean before following disinfecting instructions.) (Remove visible soil prior to application of the product.)] (This product or product name) is an effective virucide on hard, non-porous surfaces against:

- Influenza A (H1N1) Virus (ATCC VR-1469, Strain A/PR/8/34), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Bovine Viral Diarrhea Virus (BVDV) and Duck Hepatitis B Virus (DHBV) when the treated surface is allowed to remain wet for 5 minutes.
- Human Immunodeficiency Virus Type 1 (HIV-1) when the treated surface is allowed to remain wet for 2 minutes.
- Norovirus (Norwalk Virus), Feline calicivirus, and (SARS-CoV-2) (SARS -Related Coronavirus 2) (USA-WA1/2020) (BEI NR-52281) when the treated surface is allowed to remain wet for 10 minutes.

Use additional (wipe(s)) (towelette(s)) if needed to assure that the treated surface remains continuously wet for the prescribed time.

#### For Ultrasound Transducers and Probes:

Use only on external surfaces of ultrasound transducers and probes.

With a clean washcloth, clean gel from external surface of the ultrasound transducer or probe to be disinfected. Then thoroughly wet probe with (wipe(s) (towelette(s)). Treated surface must remain wet for 5 minutes. Use additional (wipe(s)) (towelette(s)) if needed to assure continuous 5 minute wet contact time. Let air dry.

**Veterinary Practice/ Animal Care Animal Laboratory/ Zoos/ Pet Shop/ Kennels/ Grooming Establishments Disinfection Directions:** For cleaning and disinfecting the following hard non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, countertops, tables, etc. Remove all animals and feed from premises, cages, crates, etc. Remove all litter, droppings and manure from equipment to be disinfected. Thoroughly clean all surfaces with soap or detergent and rinse with water. Thoroughly wet all surfaces to be treated with (wipe(s)) (towelette(s)). Treated surfaces

must remain wet for 5 minutes. Use additional (wipe(s)) (towelette(s)) if needed to assure continuous wet contact time of 5 minutes. Let air dry. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

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

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product. (This product or product name) (wipe(s) (towelette(s)) can be used for this purpose.

**CONTACT TIME:** Thoroughly wet surface with a new (product name) (wipe) (towelette). Allow surface to remain wet for 5 minutes and air dry.

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

Not for personal cleansing.

This is **not** a baby wipe!

Do not flush in toilet.

Canister Directions (Use any of the following instructions – can also use with canister icon) **TO OPEN:** 

- Remove lid from canister.
- Lift flap in center of lid.
- Pull up corner of center (wipe) (towelette) (cloth), twist to a point and thread through dispenser hole in lid. DO NOT PUSH FINGER THROUGH OPENING.
- Replace lid. Pull out exposed (wipe) (towelette) (cloth) and snap off. The next (wipe) (towelette) (cloth) pops up automatically. Dispose of used (wipes) (towelettes) (cloths) in trash receptacle. Snap center flap down when finished to retain moisture.
- Do not flush.

**TO OPEN PACKAGE:** Flip open dispensing cap and remove lid by pulling upward. Thread center (wipe) (towelette) (cloth) corner through slits in lid center. DO NOT PUSH FINGER THROUGH OPENING. Replace lid. Dispense (wipes) (towelettes) (cloths) by pulling out at an angle. Snap flip lid down when finished, to retain moisture. Dispose of used (wipes) (towelettes) (cloths) in trash. Do not flush.

**TO OPEN PACKAGE:** Pop open dispensing tab and remove top by lifting upward. Pull up corner of center (wipe) (towelette) (cloth), twist to a point and thread through slits in top. DO NOT PUSH FINGER THROUGH SLITS. Replace top and pull (wipe) (towelette) (cloth) at slight angle. The next (wipe) (towelette) (cloth) pops up automatically. Snap tab closed to retain moisture. Do not flush.

**DISPENSER:** to start feed. Remove large cover and discard seal from container. From center of (wipe) (towelette) (cloth) roll, pull up (wipe) (towelette) (cloth) corner, twist into a point and thread it through the hole in the container cover. DO NOT PUSH FINGER THROUGH HOLE. Pull through about one inch. Replace cover. Pull out first (wipe) (towelette) (cloth) and snap off at a 90 degree angle. Remaining (wipes) (towelettes) (cloths) feed automatically ready for next use. When through using, keep small center cap closed to prevent moisture loss. Do not flush.

Refillable Package Instructions: (Use with product supplied in refillable packages)

**TO OPEN PACKAGE:** Flip open dispensing flap and remove lid by lifting upward. Place (pouch) (package) in (container) (tub). Open pouch by peeling back seal. Insert (wipe) (towelette) (cloth) through opening in lid. Replace lid. The next (wipe) (towelette) (cloth) pops up automatically. When finished, close lid flap to retain moisture.

Refill Package Instructions: (Use for refill package)

**TO OPEN PACKAGE:** Flip open dispensing flap and remove lid by lifting upward. Place refill in (container) (tub). Open in (container) (tub) by peeling back seal. Insert (wipe) (towelette) (cloth) through opening in lid. Replace lid. The next (wipe) (towelette) (cloth) pops up automatically. When finished, close lid to retain moisture.

Resealable Package Instructions: (Use for product supplied in resealable pouches/packages)

**TO OPEN PACKAGE:** Slowly peel back label. (Pull out) (Remove) (wipes) (towelettes) (cloths) as needed. To retain moisture, reseal (pouch) (package) by firmly pressing label back on the (pouch) (package).

Single Use Pouch Instructions: (Use for product supplied in single use pouches/packets)

**TO OPEN PACKAGE:** Tear pouch open (along dotted line) (at tear notch) (along the top edge of pouch). (Pull out) (Remove) (wipes) (towelettes) (cloth).

For product supplied in a single use pouch with a folded towelette, include the following) Unfold (wipe) (towelette) (cloth) before use.

Center Pull Dispenser Instructions: (Use for product supplied in plastic bags)

**TO OPEN PACKAGE:** (Open lid of the dispenser.) (Cut "V" out of the top of the (plastic) bag.) (Tear open (tab on) top of (plastic) bag.) (Cut open top of (plastic) bag.) (Remove the Styrofoam core from the center of the roll.) Pull out the first (wipe) (towelette) (cloth) approximately 6 to 8 inches from the center of the roll. (Place entire bag inside of center pull dispenser. Thread the (wipe) (towelette) (cloth) through the opening on the dispenser.) (Thread the (wipe) (towelette) (cloth) through the opening on the dispenser.) (Thread the (wipe) (towelette) (cloth) through the opening on the dispenser. Place entire bag inside of center pull dispenser).

(Close the lid of the dispenser.) ((Wipe) (Towelette) (Cloth) dispensing tension may be adjusted on the bottom of the dispenser). (Additional loading directions are listed on the dispenser.) Dispenser may be mounted with (wipes) (towelettes) (cloths) (dispensing up) (dispensing down) (dispensing up or down).

#### **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

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**IF IN EYES**: Hold eyes 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. Call a poison control center or doctor for treatment advice.

(Optional) You may contact XXX/XXX-XXXX for emergency medical treatment information.

#### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE**: Store in an area inaccessible to children.

(The following Storage/Disposal statements can be used for household and Institutional/Industrial products)

#### (Optional for product supplied in nonrefillable canisters)

**CONTAINER STORAGE/DISPOSAL**: Wipes: Dispose of (wipe) (towelette) in trash after use. Do not flush. Canister: Tightly close lid between uses to retain moisture. Nonrefillable container. Do not reuse or refill this (container) (canister). Offer empty (container) (canister) for recycling if available or discard in trash.

#### (Optional for Product Supplied in Refillable Containers & Refill Package)

**CONTAINER STORAGE/DISPOSAL:** Wipes: Dispose of (wipe) (towelette) in trash after use. Do not flush. Container: Refill only with (this product) (product name). Do not reuse or refill except as described in the directions for use. Tightly close lid between uses to retain moisture. Offer empty (container) (tub) for recycling if available or discard in trash. Refill (Package) (Container) (Pouch): Nonrefillable (package) (container) (pouch). Do not reuse or refill this (package) (container) (pouch). Offer empty (container) (package) (pouch) for recycling if available or discard in trash.

#### (Optional for Product Supplied in Resealable Packages)

**CONTAINER STORAGE/DISPOSAL:** Wipes: Dispose of (wipe) (towelette) in trash after use. Do not flush. Resealable (Package) (Pouch): Reseal label between uses to retain moisture. Do not reuse or refill empty (pouch) (package). Offer empty (package) (pouch) for recycling if available or discard in trash.

#### (Optional for Product Supplied in Single Use Pouches/Packets)

**CONTAINER STORAGE/DISPOSAL:** Wipes: Dispose of (wipe) (towelette) in trash after use. Do not flush. (Pouch) or (Packet): Offer empty (pouch) (packet) for recycling if available or discard in trash.

#### (Optional for Product Supplied in plastic bags for use in Center Pull Dispensers)

**CONTAINER STORAGE/DISPOSAL:** Wipes: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Dispenser: Refill only with (this product) (product name). Do not reuse or refill except as described in the directions for use. Keep dispenser closed to retain moisture. Plastic Bag: Do not reuse or refill empty plastic bag. Offer empty plastic bag for recycling if available or discard in trash.





**Canister Directions** 







Baby crib





Door Knob

Faucet



Garbage Can



Tub and Shower walls



**Toilet (Exterior Surfaces Only)** 

Pouch/Packet Label to be used with Master Container Label

## **SCTB Wipe**

EPA REG. NO. 1839-223 EPA EST. NO. 1839-IL-01

Net Contents: 1 (Wipe) (Towelette) (Cloth)

#### **ACTIVE INGREDIENTS**

Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chlorides	0.105%
Alkyl (68% C12, 32% C14) dimethyl	
ethylbenzyl ammonium chlorides	0.105%
INERT INGREDIENTS	<u>99.790%</u>
Total	100.000%

### KEEP OUT OF REACH OF CHILDREN CAUTION

SEE (OUTER CONTAINER) (BOX) FOR PRECAUTIONARY STATEMENTS AND USE DIRECTIONS.

**DISPOSAL:** DISPOSE (WIPE) (TOWELETTE) (CLOTH) IN TRASH AFTER USE. DO NOT FLUSH. DISCARD EMPTY (POUCH) (PACKET) IN TRASH.

#### [NOTE TO REVIEWER: NOT FOR USE ON FINAL IN-COMMERCE PRODUCT LABEL] <u>Emerging Viral Pathogen Claims</u>

This product 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 indicated below:

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

• Enveloped viruses

• Large non-enveloped viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	Feline Calicivirus as a surrogate for Norovirus
Large, non-enveloped virus	Feline Calicivirus as a surrogate for Norovirus
Small non-enveloped virus	Feline Calicivirus as a surrogate for Norovirus

#### Acceptable Claim Language:

[Product Name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Feline Calicivirus 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 Feline Calicivirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [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) from above table] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information."