



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 22, 2022

Amanda Burwell
Regulatory Specialist
Stepan Company
22 Frontage Road
Northfield, IL 60093

Subject: PRIA Label Amendment – Addition of Emerging Viral Pathogen Claims
Product Name: Stepan Towelette
EPA Registration Number: 1839-174
Received Date: July 29, 2021
Action Case Number: 00314078

Dear Amanda 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. The next label printing of this product must use this labeling unless subsequent changes have been approved. 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 (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - 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 subgroup may be: small non-enveloped, large non-enveloped, or 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 or Rhinovirus Type 39 are suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms 1 through 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 section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

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 Karen Leavy via email at leavy.karen@epa.gov.



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

ACCEPTED

02/22/2022

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 1839-174

STEPAN® TOWELETTE

ACTIVE INGREDIENTS

Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)
dimethyl benzyl ammonium chlorides..... 0.105%

Alkyl (68% C₁₂, 32% C₁₄) dimethyl
ethylbenzyl ammonium chlorides..... 0.105%

INERT INGREDIENTS..... 99.790%

Total 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side (back) panels for additional precautionary statements.

EPA REG. NO. 1839-174

EPA EST. NO. (as indicated on container)

(Beginning of) (batch) (lot) code indicates EPA (Est.) (Establishment) (#) (No.) (Number)

STEPAN COMPANY

22 W. Frontage Rd.
Northfield, IL 60093

NET CONTENTS: X lbs. X ozs. (*mandatory: must be expressed in 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)" x (X)"
(e.g. 40 Pre-measured Towelettes (7" x 8") (18cm x 20cm)

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

{Note to reviewer: the following may be used to identify both the producer, supplemental distributor and a specific retailer (who is not the registrant or a supplemental distributor). Brand graphics for the company or retailer may be added to accompany identified parties}

(Manufactured by) (Made by) (Produced by) {insert producer only}

(Distributed by)(sold by)(Packed for) {insert supplemental distributor only}

(Made for) (marketed by)(sold(exclusively)by) {insert supplemental distributor or retailer that is not also a supplemental distributor}

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Amended 2/1/2022

EPA Reg. No. 1839-96

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier], <note>.

The term "this product" used throughout this document may be replaced with the marketed product brand name.

The term "x" is a place holder for numerical digits.

Punctuation and plural/singular word forms may be adjusted to allow for grammatical correctness.

Appropriate metric or imperial unit may be added as optional, supplemental information.

OPTIONAL MARKETING CLAIMS

- CLEANER
- DEODORIZER
- DISINFECTANT
- (Easy) (Effective) (Fast Effective) (Convenient) Cleaner
- CLEANS, DISINFECTS & DEODORIZES#
- *VIRUCIDE
- *VIRUCIDAL
- BACTERICIDAL
- TUBERCULOCIDAL
- PSEUDOMONICIDAL†††
†††*Pseudomonas aeruginosa* (ATCC 15442)
- (Is not abrasive to) (Will not scratch) surfaces
- Will not (bleach) (strip color from) surfaces
- Lemon Scent(ed), Fresh Scent(ed), Citrus Scent(ed), Mint Scent(ed)
- Cleans and Deodorizes in One Easy Step^
- Cuts (Tough) Grease and Grime
- Kills 99.9% of Bacteria#
- Kills 99.9% of Household Bacteria on hard, non-porous surfaces#²
- Kills 99.9% of Viruses* (and) (Bacteria) (on hard, non-porous household surfaces)
- Kills 99.9% of Germs#¹
- Kill Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)
- Meets surface disinfection recommendations from OSHA Bloodborne Pathogen Standard.
- Kills the virus that causes the common cold††
- This product has demonstrated effectiveness against rhinovirus a causative agent for colds††
†† Rhinovirus
- Use in veterinary facilities to kill canine parvovirus
- (Easily) Removes Soap Scum
- Performance in a Pouch {Note to reviewer: this is a trademarked phrase and may only be used to support MDI branded product}
- Assembled in the USA
- EFFICACY TESTS HAVE DEMONSTRATED THAT (THIS PRODUCT or PRODUCT NAME) IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).
- (Clean)(and#)(Disinfect) hard, non-porous surfaces after spills!
- (Clean)(and#)(Disinfect) hard, non-porous surfaces following a spill [(involving bodily fluids) OR (of bodily fluids)]
- (Helps) (employees)(staff) respond to clean up (and disinfection) of (blood) spills [(involving bodily fluids) OR (of bodily fluids)] on hard, non-porous surfaces
- An effective (cleaner and disinfectant#) (standardized cleaning and disinfecting procedure#) following a spill [(involving bodily fluids) OR (of bodily fluids)] on hard, non-porous surfaces
- (Can be used to)(Helps) (employers)(institutions) comply with OSHA's bloodborne pathogen standard
- Stepan Towelette (or this product or product name) is designed specifically as a general (ready-to-use) (non-abrasive) cleaner and disinfectant# for use on hard, non-porous surfaces in homes, hospitals, nursing homes, patient rooms, operating rooms, ICU areas, shower rooms, locker rooms, public restrooms, schools, food processing plants, food service establishments (restaurants) (commercial kitchens), transportation terminals, office buildings, manufacturing facilities, lodging establishments, retail businesses, veterinary clinics, pet shops, animal life science laboratories and athlete/recreational facilities where housekeeping is of prime importance in reducing cross contamination between treated hard, non-porous surfaces. It is formulated to disinfect hard, non-porous, inanimate environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, chrome, brass, copper, laminated surfaces, baked enamel surfaces, bathrooms, shower stalls, bathtubs, and cabinets. **For plastic and painted surfaces, spot test on an inconspicuous area before use.** May be used in the kitchen on counters, sinks, appliances, and stovetops when at room temperature. A rinse with potable water is required for surfaces in direct contact with food. (In addition), (this product or product name) deodorizes those areas that generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, basements, restrooms and other areas which are prone to odors caused by microorganisms.
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- For best (cleaning)(disinfection) results, always test a small inconspicuous area first.

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier], <note>.

The term "this product" used throughout this document may be replaced with the marketed product brand name.

The term "x" is a place holder for numerical digits.

Punctuation and plural/singular word forms may be adjusted to allow for grammatical correctness.

Appropriate metric or imperial unit may be added as optional, supplemental information.

- (This product or product name) is a one-step[#] (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces. Quickly removes dirt, grime, food residue, blood and other organic matter commonly found in hospitals (in health care facilities) (on medical surfaces). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.
- It cleans, disinfects and deodorizes hard, non-porous inanimate surfaces in one step[#]. Its non-abrasive formula is designed for use on (Use daily on) (Use daily to clean and disinfect) hard, non-porous inanimate surfaces: plated or stainless steel, aluminum, chrome, glazed porcelain, glazed tile, laminated surfaces associated with floors, walls, countertops, cages, crates, kennels, and animal equipment found in animal housing facilities
- When used as directed, (this product or product name) (contains 2100 ppm of active germicide making it) (is) effective against a wide variety (broad-spectrum) of pathogenic microorganisms as listed in the micro-organism table (including bacteria, antibiotic resistant bacteria, viruses.)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%[#]) (of) (has demonstrated effectiveness against) the virus that causes COVID-19^{**} on hard non-porous surfaces (in) (just) (30 seconds) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%[#]) (of) (has demonstrated effectiveness against) the virus that causes COVID-19 Coronavirus^{**} on hard non-porous surfaces (in) (just) (30 seconds) (!)
- (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 (in) (just) (30 seconds) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%[#]) (of) (has demonstrated effectiveness against) SARS-CoV-2, which causes COVID-19 on hard non-porous surfaces (in) (just) (30 seconds) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%[#]) (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) (30 seconds) (!)
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%[#]) (of) (has demonstrated effectiveness against) SARS-CoV-2 virus (the virus that causes COVID-19 illness) responsible for COVID-19 on hard non-porous surfaces (in) (just) (30 seconds) (!)
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%[#]) (of) the virus that causes COVID-19^{**} (in) (just) (One Step[#])
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%[#]) (of) the virus that causes COVID-19 Coronavirus^{**} (in) (just) (One Step[#])
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%[#]) (of) SARS-CoV-2 (the Coronavirus that causes COVID-19) (in) (just) (One Step[#])
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%[#]) (of) SARS-CoV-2, which causes COVID-19 (in) (just) (One Step[#])
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%[#]) (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[#])
- (This Product) (Product Name) Disinfects hard non-porous surfaces by killing (99.9%[#]) (of) SARS-CoV-2 virus (the virus that causes COVID-19 illness) responsible for the (COVID-19) (in) (just) (One Step[#])
- (This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%[#]) (of) (has demonstrated effectiveness against) the virus 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) the virus that causes COVID-19 Coronavirus^{**} 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%[#]) (of) (has demonstrated effectiveness against) SARS-CoV-2, which 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-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
- This Product) (Product Name) (Kills) (is) (Effective against) (Eliminates 99.9%[#]) (of) (has demonstrated effectiveness against) SARS-CoV-2 virus (the virus that causes COVID-19 illness) responsible for COVID-19 on hard non-porous surfaces
- (This Product) (Product Name) Kills (99.9%[#] of) SARS-CoV-2, which causes COVID-19 on hard non-porous surfaces

- (This Product) (Product Name) Kills (99.9%# of) SARS-CoV-2, which causes COVID-19 on hard non-porous surfaces (in) (just) (30 seconds) (!)
- This Product) (Product Name) Kills (99.9%# of) SARS-CoV-2, which 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 non-porous surfaces
- (This Product) (Product Name) Kills (is) (Effective against) the virus that causes COVID-19** on hard non-porous surfaces (in) (just) (30 seconds) (!)
- (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 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) (30 seconds) (!)
- (This Product) (Product Name) Kills SARS-CoV-2 (COVID 19 virus) (virus) on hard non-porous surfaces (in) (just) (One Step#^)
- (This Product) (Product Name) (is) Effective against SARS-CoV-2 (COVID 19 virus) on hard non-porous surfaces (in) (just) (10 minutes) (!)
- (This Product) (Product Name) (is) Effective against SARS-CoV-2 (COVID 19 virus) on hard non-porous surfaces (in) (just) (One Step#^)
- (This Product) (Product Name) (is) Effective against 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: #when used according to disinfection directions

Claim Qualifier: **Severe Acute Respiratory Syndrome Related Coronavirus 2

Claim Qualifier: ^“One Step” disinfectant claim is limited to association with non-food contact surface use.

Claim Qualifier: ¹{insert organisms from Micro-Organism table}

Claim Qualifier: ²{insert bacteria from Micro-Organism table}

Claim Qualifier: ³for use on hard, non-porous surfaces

(This product or product name) is bactericidal in the presence of organic soil (5% blood serum) against <reference bacteria organism at ATCC number if applicable from micro-organisms table> at <relevant contact time from micro-organisms table>.

(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 10 minutes contact time.

(This product or product name) is virucidal in the presence of organic soil (5% blood serum) against <reference viral organism at ATCC number if applicable from micro-organisms table> at <relevant contact time from micro-organisms table>.

(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, CAT labs, CCU, Central Supply, 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, Pediatric Intensive Care Units (PICU), Physical therapy, Physician’s office(s), Ophthalmic offices, Radiology, Recovery Room, Rehabilitation, Respiratory therapy, Surgery, Transport vehicles, X-Ray

(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, Ophthalmic 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# hard, non-porous, surfaces of: bed railings, cabinets, carts, chairs, counters, exam tables, gurneys, isolettes, IV poles, stethoscopes, stretchers, tables, telephones, toilet seats, toilet exterior, bathtubs, bathroom fixtures, shower stalls, sinks, tiles, vanity tops, hospital beds, traction devices, MRI, CAT, 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# hard, non-porous surfaces of: changing tables, cribs, diaper pails, trashcans, garbage cans.

(This product or product name) will clean and disinfect# 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# 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.

SUBSTRATE CONTENT CLAIMS

{Note to reviewer: The following claims may only be used if the supplemental registrant or Stepan has documentation to support claims}

- (Substrate) (Wipe fabric) (Towelette fabric) (Cloth) made (of) (from) (minimum) (up to) (XX%) (regenerated) (recycled) (cellulose) (wood pulp) (plant based) (sources) (materials) (resources)
- Wipe [(Substrate) (Towelette fiber(s)) (Cloth)] (are) (is) (made from) (contains) (regenerated) (recycled) (cellulose) (wood pulp) (plant based) (sources)
- Wipe [(fabric)(material)(substrate)] made from (minimum) (up to) (XX%) (wood pulp) (plant based) (ingredients) (fibers)
- Made with Lyocell® (the) (ultra-soft) (soft) (strong) (durable) (resource) (fiber)(s)
- Wipe [(fabric)(material)(substrate)] [(made) (derived)] from (minimum) (up to) (XX%) (post consumer) (recycled) plastic (water) bottles

MICRO-ORGANISMS

BACTERICIDAL ACTIVITY (BACTERIA): (Using AOAC test methods (under Good Laboratory Practices, (GLPs)), in the presence of 5% blood serum and a 10 minute contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard non-porous inanimate surfaces:)		
Organism	Strain ID	Contact Time
<i>Pseudomonas aeruginosa</i>	(ATCC 15442)	3 minutes
<i>Staphylococcus aureus</i>	(ATCC 6538)	3 minutes
<i>Salmonella (choleraesuis) enterica</i>	(ATCC 10708)	3 minutes
<i>Escherichia coli</i>	(ATCC 11229)	3 minutes
<i>Escherichia coli O157:H7</i>	(ATCC 43895)	3 minutes
<i>Streptococcus pyogenes</i> (Necrotizing Fasciitis-Group A)	(V.A. Medical Center Isolate 04001)	3 minutes
<i>Listeria monocytogenes</i>	(ATCC 35152)	3 minutes
<i>Yersinia enterocolitica</i>	(ATCC 23715)	3 minutes
<i>Enterococcus faecium</i>	(ATCC 6569)	3 minutes
<i>Corynebacterium ammoniagenes</i>	(ATCC 6871)	3 minutes
<i>Salmonella (typhi) enterica</i>	(ATCC 6539)	3 minutes
ANTIBIOTIC-RESISTANT (STRAINS OF) (ANTIBIOTIC-RESISTANT BACTERICIDAL ACTIVITY): (Using AOAC test methods (under Good Laboratory Practices, (GLPs)), in the presence of 5% blood serum and a 10 minute contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard non-porous inanimate surfaces:)		
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	(ATCC 33593)	3 minutes
Vancomycin resistant <i>Enterococcus faecalis</i> (VRE)	(ATCC 51575)	3 minutes
Vancomycin intermediate resistant <i>Staphylococcus aureus</i> (VISA)	(CDC Isolate 99287)	3 minutes
Methicillin resistant <i>Staphylococcus epidermidis</i> (MRSE)	(ATCC 51625)	3 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	(NRS 123) Genotype USA400	3 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	(NRS 384) Genotype USA300	3 minutes
VIRUCIDAL ACTIVITY (Viruses)		
Virus Enveloped	ATCC Number	Contact Time
HIV-1 (associated with AIDS)	Zeptomatrix IIIB (B)	1 minute
Influenza A (H1N1) Virus	(ATCC VR-1469)	5 minutes
Avian Influenza A strain H3N2	(ATCC VR-2072)	2 minutes
Avian Influenza A strain H9N2	SPAFAS	2 minutes
Hepatitis B Virus (HBV)	Hepadnavirus Testing, Inc.	1 minute
Hepatitis C Virus (HCV)	American BioResearch Laboratories	1 minute
Duck Hepatitis B Virus (DHBV)	HepadnaVirus Testing, Inc.	1 minute
Bovine Viral Diarrhea Virus (BVDV)	American BioResearch Laboratories	1 minute
Human Coronavirus	(ATCC VR-740)	2 minutes
SARS associated Coronavirus	Zeptomatrix	2 minutes
SARS-Related Coronavirus 2 (SARS-CoV-2)	USA-WA1/2020 BEI NR-52281	30 seconds
Rabies Virus	Attenuated ERA strain, CDC	1 minute
Paramyxovirus (Mumps)	(ATCC VR-1438)	3 minutes
Virus Large Non-Enveloped		
Rotavirus	(ATCC VR-2018)	3 minutes

<i>Virus Small Non-Enveloped</i>		
Norovirus (Norwalk virus)	(ATCC VR-782)	1 minute
Feline Calicivirus	(ATCC VR-782)	1 minute
Canine Parvovirus	(ATCC VR-2017)	5 minutes
Poliovirus Type 1	(ATCC VR-1000)	10 minutes
Rhinovirus type 39	(ATCC VR-340)	3 minutes

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.

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

CLEANING: Use one (product name) (wipe) (towelette) to completely remove surface of 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 disinfection:

- To disinfect against *<reference bacterial organism and ATCC number, if applicable, from micro-organisms table>*, allow the treated surface to remain wet for 3 minutes.
- To disinfect against *Mycobacterium bovis* BCG (Tuberculosis), allow the treated surface to remain wet for 10 minutes.

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:

{Note to reviewer, use one or more of the following statements depending on desired organisms list. Viruses with a shorter contact time may be included into a statement for longer contact times if desired.}

- *<Reference viral organism and ATCC number, if applicable, from micro-organisms table>*, when the treated surface is allowed to remain visibly wet for 10 minutes.
- *<Reference viral organism and ATCC number, if applicable, from micro-organisms table>*, when the treated surface is allowed to remain visibly wet for 5 minutes.
- *<Reference viral organism and ATCC number, if applicable, from micro-organisms table>*, when the treated surface is allowed to remain visibly wet for 3 minutes.
- *<Reference viral organism and ATCC number, if applicable, from micro-organisms table>*, when the treated surface is allowed to remain visibly wet for 2 minutes.
- *<Reference viral organism and ATCC number, if applicable, from micro-organisms table>*, when the treated surface is allowed to remain visibly wet for 1 minute.
- SARS-CoV-2 (associated with COVID-19), when the treated surface is allowed to remain visibly wet for 30 seconds.

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 visibly wet for (5 minutes) (or) (10 minutes). Use additional (wipe(s)) (towelette(s)) if needed to assure that the treated surface remains continuously wet for the prescribed time. Let air dry. {Note to reviewer, 10 minute contact time must be used when Poliovirus Type 1 is referenced on the label}

(The following statements must be used for Bloodborne Pathogens: HIV-1, HBV and HCV:)

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.

CONTACT TIME: Allow surface to remain visibly wet for 1 minute. This contact time will not control other common types of viruses and bacteria.

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.

Note to reviewer: The following advisory statements are optional. These statements are intended for products sold in state or local jurisdictions that have phosphate restrictions or limits for cleaners. One of the statements can be selected and placed with the Directions for Use section as applicable.}

ADVISORY STATEMENTS

- Formulation meets state and local restrictions for phosphate content in hard surface cleaners
- Does not contain (phosphates) (phosphorous) (as required per state and/or local requirements)

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 (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. 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).

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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 or using tobacco.

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.

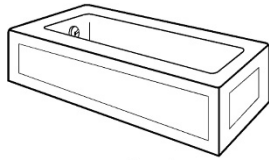
(Optional for Product Supplied in plastic bags for use in Center Pull Dispensers)

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.

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

GRAPHICS

Note to Reviewer: These are representative icons / descriptions for use sites/application methods that may appear on the label listed in the location/surfaces section of this label with the appropriate directions for use, PPE or package type.)



Bathtub



Canister Directions



Changing Table



Computer



Baby crib

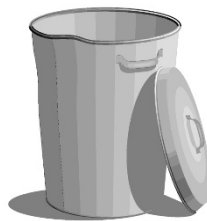
3



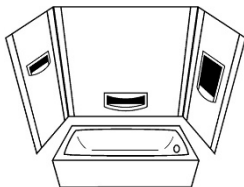
Door Knob



Faucet



Garbage Can



Tub and Shower walls



Toilet (Exterior Surfaces Only)

(OR)
(sink with faucet)
(work station tub or sink)
(rubber gloves) (masks³) (PPE)
(table)
(chair)
(wall)
(cabinet)
(doorknob)

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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(garbage can)
(non-wooden picnic table)
(outdoor furniture except cushions and wood frames).
(Telephone)
(non-food contact counter tops, equipment, shelves, racks and carts)
(shower stalls)
(shower doors and curtains³)
(tubs)
(glazed tiles)
(toilets- must note exterior surfaces only)
(urinals- must note exterior surfaces only)
(glazed porcelain tile) and (restroom fixtures).
(vehicle) (boat) (RV) (trailer)
(recycling logo) {Note to reviewer: Only for containers which may be recycled per storage and disposal directions}
(American flag logo) {Note to reviewer: May only be used on labels which carry "Assembled in USA" or "Assembled in America" marketing statements.}
(Brand or Company name specific graphics, logos, and stylized fonts including background patterns and fill colors)
(Women owned business logos or other business industry membership logos)
(Do not flush icons)

{Note to reviewer the exact virus image below may be used in association with SARS-CoV-2 marketing claims and applicable directions for use as a stylized graphic including any of the following statements: "Kills (the) COVID-19 Virus^{3**}"; "Effective against SARS-CoV-2³"; "Kills SARS-CoV-2 (in) (just) (30 seconds)³".}



{Note to reviewer: Qualifier 3 must be used in conjunction with the stylized virus graphic with marketing text as described above}

Pouch/Packet Label to be used with Master Container Label

STEPAN® TOWELETTE

EPA REG. NO. 1839-174
EPA EST. NO. 1839-IL-01

Net Contents: X lbs. X ozs. (*mandatory: must be expressed in pounds and ounces*)

Optional: can also be expressed as total count

1 (Wipe) (Towelette) (Cloth)

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.105%
Alkyl (68% C ₁₂ , 32% C ₁₄) 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.

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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Amended 02/17/2022

{NOTE TO REVIEWER: NOT FOR USE ON FINAL IN-COMMERCE PRODUCT LABEL}

Emerging Viral Pathogen Claims

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
- Small non-enveloped viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Feline Calicivirus, ATCC VR-782 (surrogate for Norovirus)
Large, non-enveloped virus	Feline Calicivirus, ATCC VR-782 (surrogate for Norovirus)
Small non-enveloped virus	Rhinovirus Type 39 (ATCC VR-340) Feline Calicivirus, ATCC VR-782 (surrogate for Norovirus)

Acceptable Claim Language:

[Product Name] has demonstrated effectiveness against viruses similar to ***[name of emerging virus]*** on ***hard, non-porous surfaces***. Therefore, ***[product name]*** can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***hard, non-porous surfaces***. Refer to the ***[CDC or OIE]*** website at ***[pathogen-specific website address]*** for additional information.

[Name of illness/outbreak] is caused by ***[name of emerging virus]***. ***[Product name]*** kills similar viruses and therefore can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***hard, non-porous surfaces***. Refer to the ***[CDC or OIE]*** website at ***[website address]*** for additional information." ***[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."