



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

MAR 25 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Thomas W. Isaac
Sr. Regulatory Specialist
Stephan Company
22 W. Frontage Rd.
Northfield, IL 60093

Subject: **SCTB Wipe**
EPA Registration Number 1839-223
Application Dated September 8, 2009
EPA Receive Date September 9, 2009

Dear Mr. Isaac:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendment:

- Add Influenza A (H1N1) Virus claim

Labeling Comments:

1. Page four of the proposed label, under Directions for Use, lists separate options for disinfection for differing organisms (i.e. "To disinfect against *Escherichia coli*....," "To disinfect against *Mycobacterium bovis* BCG....," "To disinfect against *Staphylococcus aureus*..."). These directions need to indicate that the treated surface must remain wet 5 five minutes to disinfect, in order to be clear to the end user. Separate claims for organisms and contact times may be listed elsewhere on the label.
2. Similarly, on page 5, under Special Instructions for HIV/Body Fluids, instead of saying, "Although efficacy at a 2 minute contact time has been shown to be adequate against HIV-1, use the contact time for the disinfection of other organisms listed on label," the label needs to state, "Allow the surface to remain wet for a 5 minute contact time."

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Velma Noble

Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: stamped label , Efficacy review approval dated 1/27/10

SCTB Wipe

(Optional statements:)

CLEANER // NEW // QUICK // EASY // EFFECTIVE // FAST EFFECTIVE
// CONVENIENT

CLEANS, DISINFECTS & DEODORIZES
MULTI-PURPOSE CLEANER

ANTIBACTERIAL FORMULA CLEANS and DISINFECTS

CITRUS SCENTED // FRESH SCENTED // LEMON SCENTED // MINT SCENTED //

*VIRUCIDAL//TUBERCULOCIDAL//BACTERICIDAL//PSEUDOMONICIDAL

Cleans and Deodorizes in One Easy Step

Cuts (Tough) Grease and Grime

Kills 99.9% of Bacteria

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.

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

MAR 25 2010

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

EPA REG. NO. 1839-223

EPA EST. NO. 1839-IL-01

STEPAN COMPANY

22 W. Frontage Rd.
Northfield 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)" x (X)"
(e.g. 40 Pre-measured Towelettes (7" x 8") (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* (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* (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_B (HIV-1) (associated with AIDS) at 2 minutes contact time and Influenza A (H1N1) Virus (ATCC VR-1469, Strain A/PR/8/34) at 5 minutes contact time.

(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, toilets, 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.

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: Use one (product name) (wipe) (towelette) to completely remove surface of all gross debris from surfaces to be treated.

DISINFECTING: To disinfect hard, non-porous surfaces, thoroughly wet the surface to be treated. Treated surface must remain visibly wet for disinfection:

- To disinfect against *Escherichia coli* (*E. coli*), *Escherichia coli* O157:H7, *Pseudomonas aeruginosa*, *Salmonella (choleraesuis) enterica* and Vancomycin Resistant *Enterococcus* (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.

For heavily soiled surfaces, clean before following disinfecting instructions.

***VIRUCIDAL ACTIVITY:** (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) 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.

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 10 minutes. Use additional (wipe(s)) (towelette(s)) if needed to assure continuous 10 minute wet contact time. Let air dry.

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KILLS HIV-1 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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 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 air dry. Although efficacy at a 2 minute contact time has been shown to be adequate against HIV-1, use the contact time for the disinfection of other organisms listed on this label.

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. 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 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.

CONTAINER DISPOSAL: Do not reuse empty (container) (canister). Rinse thoroughly before discarding in trash.

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

CONTAINER STORAGE/DISPOSAL: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Tightly close lid between uses to retain moisture. Do not reuse empty container except with refill, otherwise discard in trash.

(Optional for Product Supplied in Resealable Packages)

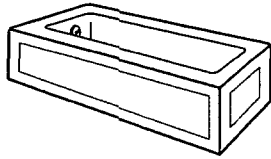
CONTAINER STORAGE/DISPOSAL: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Reseal label between uses to retain moisture. Do not reuse empty (pouch) (package). Discard empty (pouch) (package) in trash.

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

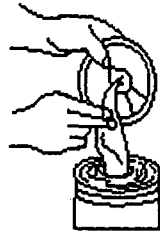
CONTAINER STORAGE/DISPOSAL: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Discard empty (pouch) (packet) in trash.

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

CONTAINER STORAGE/DISPOSAL: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Keep dispenser closed to retain moisture. Do not reuse empty plastic bag. Discard empty plastic bag in trash.



Bathtub



Canister Directions



Changing Table



Computer



Baby crib



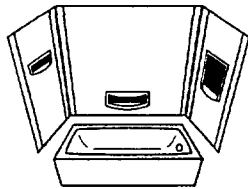
Door Knob



Faucet



Garbage Can



Tub and Shower walls



Toilet

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 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.