

1839-174

09/02/2005

1/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobial Division (7510C)  
1200 Pennsylvania Ave. NW  
Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

1839-174

SEP - 2 2005

Term of Issuance:

Conditional

Name of Pesticide Product:

Stepan Towelette

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):  
Stepan Company  
22 W. Frontage Rd.  
Northfield, IL 60093

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label changes:
  - a. Revise the EPA Registration Number to read, "EPA Reg. No." 1839-174"
3. Submit two (2) copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of this product constitutes acceptance of these conditions.

A stamped label is enclosed for your records. If you have any questions regarding this letter, please contact Zenobia Jones at (703) 308-6198.

Signature of Approving Official:

*Velma Noble*  
Velma Noble  
Product Manager 31

Date:

SEP - 2 2005

Regulatory Management Branch I

CONCURRENCES

SYMBOL	SURNAME	DATE				
	Z. Jones	09-02-05				

page 2

EPA Reg. No. 1839-174

### **ACUTE TOXICITY**

1. The Signal word is "Caution".
2. The precautionary statements are:  
"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".
3. The First Aid statements should state:  
  
"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 five minutes, then continue rinsing.  
Call a Poison Control Center or doctor for treatment advice.

### **EFFICACY**

The submitted efficacy data support the effectiveness of the product, Stepan Towelette, as a disinfectant against the microorganisms in the presence of a 5% organic soil load on hard, non-porous surfaces for the contact time that is listed. (See enclosed Efficacy review).

**NOTE:** This registration is acceptable with conditions. Until additional data are provided, the organisms ( Trichophyton mentagrophytes and Poliovirus type 1) must be deleted from the label. Also, the statement referencing Klebsiella pneumoniae and Staphylococcus aureus as an effective sanitizer for hard non-porous, pre-cleaned, non-food contact surfaces in 1 minute must be removed from the label.

### **PRODUCT CHEMISTRY**

The product Science Branch of the Antimicrobial Division finds this submission in support of the registration for 1839-RIU to be acceptable. (See enclosed Chemistry review)

3/10

# STEPAN TOWELETTE

(Optional statements:)

**KILLS 99.9% OF BACTERIA** (*Klebsiella pneumoniae*, ATCC 4352 and *Staphylococcus aureus*, ATCC 6538) in (1 minute)(60 seconds)

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

**CLEANS, DISINFECTS & DEODORIZES**

**ALL PURPOSE CLEANER**

**KILLS GERMS**

**ANTIBACTERIAL FORMULA CLEANS and DISINFECTS**

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

**BLEACH-FREE // ALCOHOL-FREE**

**\*VIRUCIDAL//TUBERCULOCIDAL//BACTERICIDAL//PSEUDOMONICIDAL**

### ACTIVE INGREDIENTS

Alkyl (80% 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% C<sub>12</sub>, 32% C<sub>14</sub>) dimethyl

ethylbenzyl ammonium chlorides.....0.105%

**INERT INGREDIENTS.....99.790%**

Total 100.000%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

See side panels for additional precautionary statements.

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

### STEPAN COMPANY

22 W. Frontage Rd.  
Northfield 60093

NET CONTENTS:

X Pre-measured (Pre-moistened) (Wipes) (Towelettes) (Cloths) (X)" x (X)"  
(e.g. 40 Pre-measured Wipes (7" x 8") (18cm x 20cm)

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 2 - 2005

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

(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* ATCC, *Pseudomonas aeruginosa* ATCC 15442, and Vancomycin Resistant *Enterococcus* (VRE) ATCC 51575 at 2 minutes contact time and against *Staphylococcus aureus* ATCC 8538 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 Vancomycin Intermediate Resistant *Staphylococcus aureus* (VISA), Clinical Isolate No. 99286, at 10 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 and against Norwalk Virus, Feline Calicivirus (FCV), Poliovirus Type 1 ATCC VR-1000 at 10 minutes contact time.

(This product or product name) is virucidal in the presence of organic soil (5% blood serum) against Norwalk Virus, Feline Calicivirus (FCV), Poliovirus Type 1 ATCC VR-1000 at 10 minutes contact time.

(This product or product name) is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* ATCC 9533 (causative agent of Athlete's Foot Fungus) (a cause of Ringworm) (a cause of Ringworm of the foot) at 10 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 recommended 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 or product name) kills 99.9% of bacteria: *Klebsiella pneumoniae* ATCC 4352 and *Staphylococcus aureus* ATCC 8538) in 1 minute (60 seconds) on hard, non-porous surfaces.

6/10

**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 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* and Vancomycin Resistant *Enterococcus* (VRE), allow the treated surface to remain wet for 2 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.
- To disinfect against Vancomycin Resistant *Staphylococcus aureus* (VISA), allow the treated surface to remain wet for 10 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:

- Human Immunodeficiency Virus Type 1 (HIV-1) when the treated surface is allowed to remain wet for 2 minutes.
- Norwalk Virus, Poliovirus, Feline calicivirus when the treated surface is allowed to remain wet for 10 minutes.

**FUNGICIDAL ACTIVITY:** (This product or product name) is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus) (a cause of Ringworm) (a cause of Ringworm of the foot) when hard, non-porous treated surfaces found in bathrooms, shower stalls, locker rooms or other surfaces commonly contacted by bare feet are 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.

**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, or 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 recommended contact time for the disinfection of other organisms listed on this label.

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

**SANITIZATION OF NON-FOOD CONTACT SURFACES:** To sanitize hard, non-porous, pre-cleaned surfaces use (this product or product name) (wipe(s)) (towelette(s)) to thoroughly wet the surface. Allow treated surface to remain wet for 1 minute (60 seconds) then let air dry or remove excess liquid. For heavily soiled areas, use (this product or product name) to pre-clean the surface. (This product or product name) kills 99.9% of *Klebsiella pneumoniae* ATCC 4352 and *Staphylococcus aureus* ATCC 8538.

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).



9/10

**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.

**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 eyelids 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 the eye. 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.

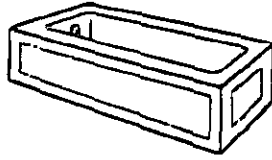
*(Optional for Product Supplied in Refillable Containers & Refill Package)*

**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.

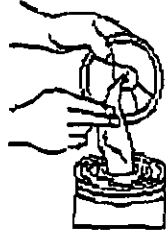
*(Optional for Product Supplied in Resealable Packages)*

**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.

10/10



**Bathtub**



**Canister Directions**



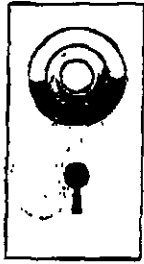
**Changing Table**



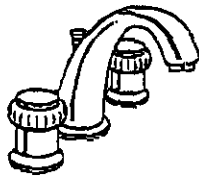
**Computer**



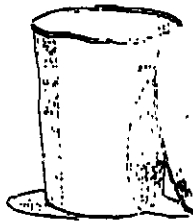
**Baby crib**



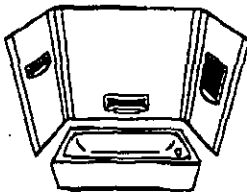
**Door Knob**



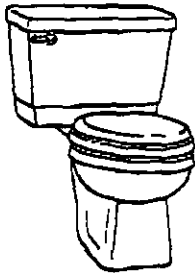
**Faucet**



**Garbage Can**



**Tub and Shower walls**



**Toilet**