



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

FEB 14 2006

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Solvent Free Disinfectant Wipes
EPA Registrant No. 1839-178
Application Date: August 1, 2005
Receipt Date: August 3, 2005

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:

- . Removed the "Limited Disinfectant" claim
- . Addition of Hospital (Medical Institution) Nursing Home) use site and environmental Surfaces
- . Addition of disinfecting claims vs. bacteria
- . Addition of virucidal claims vs. viruses
- . Addition of Non-Food Contact Surface Sanitation claims
- . Addition of miscellaneous marketing claims

PRODUCT CHEMISTRY

1. The concentrations of the active ingredients on the Confidential Statements of Formula (CSFs dated 8/1/05 for the basic formulation and alternate 1) are consistent with the label declaration. These CSFs supersede all previous CSFs for these formulations.
2. All ingredients are cleared for use in pesticidal products.
3. All certified limits are calculated correctly.

The Product Science Branch of the Antimicrobials Division finds the submission for 1839-178 to be acceptable.

accepted.

5. On pages one and three, the applicant should change "Camphylobacter jejuni" to read "Caraphylobacter jejuni".
6. The use directions should be revised to include verbiage to use the textured surface of the towelette, as this is consistent with verbiage detailed in the efficacy studies.

GENERAL COMMENTS

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies 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 Zenobia Jones at (703) 508-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

SOLVENT FREE DISINFECTANT WIPES

(Optional statements:)

KILLS 99.9% OF (SOME) GRAM NEGATIVE & GRAM POSITIVE BACTERIA
CLEANER // NEW // QUICK // EASY // EFFECTIVE // FAST EFFECTIVE //
CONVENIENT

CLEANS, DISINFECTS & DEODORIZES
ALL PURPOSE CLEANER

KILLS 99.9% OF (SOME) BACTERIA * (requires disinfection use directions)

KILLS 99.9% OF BACTERIA# in 3 minutes (requires sanitizer use directions)

CLEANS STREAK-FREE

ANTIBACTERIAL FORMULA CLEANS and DISINFECTS

CITRUS// FRESH// LEMON (SCENT) (SCENTED) (FRAGRANCE)

BLEACH-FREE // ALCOHOL-FREE // DISINFECT AND TOUCH-UP CLEAN ANYTIME

SANITIZER—Non-Food Contact Surfaces

VIRUCIDAL

BACTERICIDAL

(*If this claim is made, organisms must be listed as follows:)

*Salmonella choleraesuis (Salmonella), Escherichia coli (E. coli), Staphylococcus aureus (Staph),
Pseudomonas aeruginosa, Streptococcus pyogenes (Strep), and Escherichia coli (E. coli) O157:H7

(*If this claim is made, organisms must be listed as follows:)

*Salmonella choleraesuis (Salmonella), Staphylococcus aureus (Staph), Klebsiella pneumoniae,
Escherichia coli (E. coli) O157:H7, Campylobacter jejuni, and Listeria monocytogenes

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride	0.03990%
Diocetyl dimethyl ammonium chloride	0.01995%
Didecyl dimethyl ammonium chloride	0.01995%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	0.05320%
INERT INGREDIENTS	99.86700%
Total	100.00000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See (side) (back) panels for additional precautionary statements.

EPA REG. NO. 1839-178
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") (17.8cm x 20.3cm))

ACCEPTED
with COMMENTS
Date: FEB 14 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
1839-178

(Optional additional bullet points for label)

- (Antibacterial) (Disinfecting) (Bactericidal) and scrubbing power all in one
- (All)(Multi) (purpose) (surface)
- Non-scratching (Non-abrasive)
- The (wipe) (towelette) (cloth) that is (strong) (durable) (thick) (heavy) enough to scrub (and) (clean)
- (Textured cloth) gets up stubborn stuck on messes
- Will not scratch (Non-scratching)
- (After use), just toss wipe away (in trash) (in garbage)
- Cleans because the (scrubbies) (texture) remove(s) (stubborn) (stuck on) (dirt) (messes)
- Dual (action) (purpose)
- Scrubs like no other (wipe) (towelette) (cloth)
- (Pre-moistened) (wet) disinfecting (textured) (wipe) (towelette) (cloth) (for tough jobs)
- Scrubbing (wipe) (towelette) (cloth)
- Wipes and scrubs
- An effective way to clean and deodorize against odor-causing bacteria
- The (wipe) (towelette) (cloth) that cleans (up (stubborn) (stuck-on) messes) (so you don't have to get on your hands and knees)
- Leaves a clean, fresh scent
- Leaves your (bathroom) (kitchen) fresh and clean
- Lint free
- Effective in the presence of 5% serum contamination
- Clean with just a wipe or a touch up
- Easy to use
- For (light touch ups) (quick clean-ups) (in one easy step)
- For household surfaces (all around the house) indoor and outdoor
- For use (at home), (away from home), (in public places) (on the go)
- For when a regular (wipe) (towelette) (cloth) (just) can't get the job done
- Great for cleaning around the toilet
- Handles daily clean-ups with no need for additional sprays or buckets
- Heavy (light) duty jobs
- Just (pull) (pop), wipe and toss away (in trash) (in garbage)
- Makes (your job) (cleaning) (easier) (easy)
- No (mixing) (spraying) (mess) (and/or fuss)
- One step (clean) (cleaning)
- Quick easy clean-ups
- Saves (time) (steps)
- The smart (way to) clean (disinfect) and (sanitize)
- Use (daily) to clean bathroom soils such as soap, soap scum, toothpaste, hair spray, hair gel, cosmetics, shaving cream, hand or body lotion
- Use at the (gym) (health club) on (exercise equipment) (apparatus) (sinks) (toilet seats)
- For use in (medical institutions), (hospitals), and (nursing homes)
- (This product or product name) is formulated to disinfect the following hard, non-porous, inanimate, environmental surfaces: (hospital beds), (traction devices), (MRI), (CAT), (examining tables), (scales), (paddles), (wheelchairs), (ultrasonic baths), and (whirlpools).

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 institutions, hospitals, nursing homes, and metal and/or stainless steel surfaces, the following statement must be used)

(This product or product name) is not for use on critical or semi-critical medical devices.

(POTENTIAL LABEL CLAIMS:)

(Select any one of the following)	Followed by: (Select any one or more of the following)	May be followed by: (Select any one or more of the following)
Sanitizes in 3 minutes against [#]	* <i>Salmonella choleraesuis</i> (Salmonella), <i>Staphylococcus aureus</i> (Staph), <i>Klebsiella pneumoniae</i> , <i>Escherichia coli</i> (E. coli) O157:H7, <i>Camphylobacter jejuni</i> , <i>Listeria monocytogenes</i>	Found on hard, non-porous (kitchen) (and) (bathroom) (restroom) (shower and bath areas) surfaces
Clean(s)	** <i>Salmonella choleraesuis</i> (Salmonella), <i>Escherichia coli</i> (E. coli), <i>Staphylococcus aureus</i> (Staph), <i>Pseudomonas aeruginosa</i> , <i>Streptococcus pyogenes</i> (Strep), <i>Escherichia coli</i> (E. coli) O157:H7, Influenza A ₂ Hong Kong, Herpes Simplex Virus 2.	Found in (locker rooms) (health clubs) (athletic facilities) (barber shops) (restaurants) (correctional facilities) (dressing rooms) (factories) (hotels) (motels) (salons) (schools) (sick rooms) (play ground equipment) (emergency vehicles) (transportation terminals) (daycare facilities)
Kills germs**	(Medical Institutions) (Hospitals) (Nursing Homes) (Household) (Kitchen) (Bathroom) Bacteria*	From hard, non-porous Bathroom (restroom) surfaces
Kill(s)	99.9% of (some) bacteria *	(one or more of the following surfaces):
Removes(s)	99.9% of some Household/Kitchen/Bathroom Bacteria*	kitchen counters, sealed stone, stovetops, sinks, the outside of microwaves, refrigerators and other similar appliances, walls, countertops, finished hardwood, cabinets, floors, exterior toilet bowl surfaces, diaper pails, trash cans, glazed tile, tubs, diaper changing (tables) (counters), sinks, chrome, shower walls, bathrooms, public restrooms, door knobs, faucets, telephone receivers and key pads, patio furniture, cribs, car interiors, computers, hand rails, wall switch plates, door frames, restrooms, urinals, desks, and dining room surfaces
Effective Against	Odor causing bacteria*	
Wipes Away	* <i>Salmonella choleraesuis</i> (Salmonella), <i>Escherichia coli</i> (E. coli), <i>Staphylococcus aureus</i> (Staph), <i>Pseudomonas aeruginosa</i> , <i>Streptococcus pyogenes</i> (Strep), <i>Escherichia coli</i> (E. coli) O157:H7	
Are thick pre-moistened antibacterial wipes that remove		
Easily removes		
Cleans streak-free and kills		
Disinfects (against)		

CLEANING: Wipe surface with (wipe) (towelette) (cloth), let air dry. No need to rinse. These (wipes) (towelettes) (cloths) will not harm most surfaces. Not recommended on unpainted wood or glass.

DISINFECTION and DEODORIZATION: Wipe surface to be disinfected. Allow surface to remain wet for 10 minutes before use. Let surface dry. A rinse is required for surfaces in direct contact with food. (No scrubbing is necessary.) (The product will not leave grit or soap scum.) For heavily soiled surfaces, clean before following **Disinfection** instructions.

Not for personal cleansing. This is not a baby wipe!

BACTERICIDAL ACTIVITY - When used as directed, this product exhibits effective disinfectant activity against the organisms: *Salmonella choleraesuis* (Salmonella), *Escherichia coli* (E. coli), *Escherichia coli* (E. coli) O157:H7, *Staphylococcus aureus* (Staph), *Pseudomonas aeruginosa*, *Streptococcus pyogenes* (Strep).

[#] VIRUCIDAL ACTIVITY - When used as directed, this product exhibits effective virucidal activity against the organisms: Influenza A₂ Hong Kong, Herpes Simplex Virus 2.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

TO SANITIZE and DEODORIZE NON-FOOD CONTACT SURFACES: Wipe surface until thoroughly wet. Let stand 3 minutes. For heavily soiled areas a pre-cleaning step is required. This product is an effective sanitizer against *Klebsiella pneumoniae*, *Staphylococcus aureus* (Staph), *Escherichia coli* (E. coli) O157:H7, *Camphylobacter jejuni*, and *Listeria monocytogenes*

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).

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.

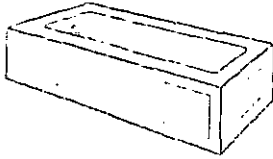
CONTAINER DISPOSAL: Do not reuse empty (container) (canister). Rinse thoroughly before discarding in trash.

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

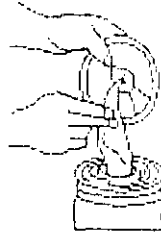
CONTAINER STORAGE/DISPOSAL: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Tightly close lid between uses to retain moisture. Do not reuse empty container except with refill, otherwise discard in trash.

(Optional for Product Supplied in Resealable Packages)

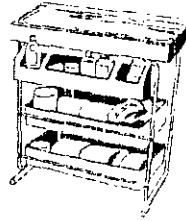
CONTAINER STORAGE/DISPOSAL: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Reseal label between uses to retain moisture. Do not reuse empty (pouch) (package). Discard empty (pouch) (package) in trash.



Bathtub



Canister Directions



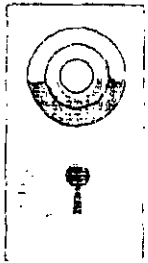
Changing Table



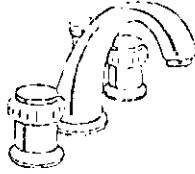
Computer



Baby crib



Door Knob



Faucet



Garbage Can



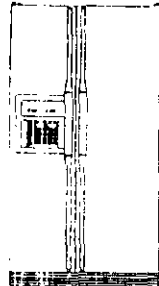
**Kitchen
Countertops**



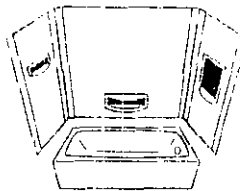
**Outside of
microwaves**



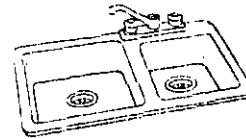
Patio Furniture



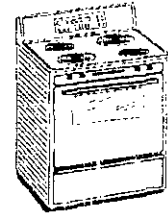
**Outside of
Refrigerator**



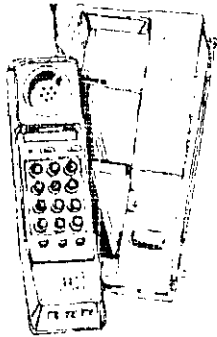
Tub and Shower walls



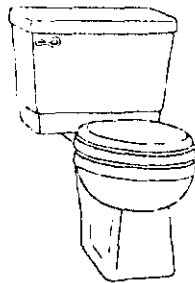
Sinks



Stovetop



**Telephone Receivers
and Key Pads**



Toilet