

1839-223

05-06-2010

1/13

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 6 2010

Mr. Thomas W. Isaac
Senior Regulatory specialist
Stephen Company
22 W. Frontage Rd.
Northfield, Illinois 60093

Subject: **SCTB Wipe**
EPA Registration Number 1839-223
Notification Application Dated April 5, 2010
EPA Received Date April 8, 2010

Dear Mr. Isaac:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Addition of the species name "faecalis" to the organism Vancomycin Resistant Enterococcus (VRE)
- Removal of the marketing claim "Cuts (tough) Grease and Grime"

General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

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

Sincerely,
Drusilla Copeland
Velma Noble
Product Manager (31)

Regulatory Management Branch I
Antimicrobials Division (7510F)

SYMBOL							
SURNAME							
DATE							

34-27

2/15

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1839-223	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SCTB Wipe	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage Rd. Northfield, IL 60093 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

1. Addition of the species name "faecalis" to the organism Vancomycin Resistant Enterococcus (see pages 2 &4).
2. Removal of the marketing claim "Cuts (Tough) Grease and Grime" from page 1 of label.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container 35-135	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 35-135/canister		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Thomas W. Isaac	Title Sr. Regulatory Specialist	Telephone No. (Include Area Code) (847) 501-2309
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) _____ _____ _____
2. Signature <i>Thomas W. Isaac</i>	3. Title Sr. Regulatory Specialist	
4. Typed Name Thomas W. Isaac	5. Date April 5, 2010	



April 5, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Antimicrobials Division
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Ms. Velma Noble
PM-31
Regulatory Management Branch I

RE: SCTB Wipe
EPA Reg. No. 1839-~~223~~ 223

Dear Ms. Noble:

This Notification proposes the following label revisions:

1. Addition of the species name "faecalis" to the organism Vancomycin Resistant *Enterococcus* (VRE), see pages 2 & 4.
2. Removal of the marketing claim "Cuts (tough) Grease and Grime" from page 1 of label.

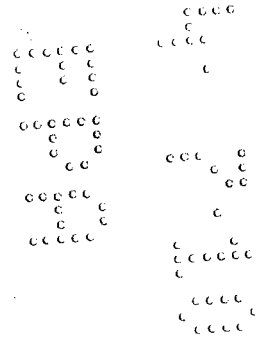
Five (5) draft labels are enclosed. One label is highlighted for Agency review.

Should the Agency need additional information in order to process this notification, please feel free to contact me immediately at (847) 501-2309 or via email: tisaac@stepan.com.

Sincerely,
STEPAN COMPANY

Thomas W. Isaac
Sr. Regulatory Specialist

Enclosures: Amendment administrative package, labels (5 copies)
TWI:sif



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

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.

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

NOTIFICATION

Date Reviewed: 5/6/10
Reviewed By: D.C.

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

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

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

(This product or product name) is virucidal in the presence of organic soil (5% blood serum) against Human Immunodeficiency Virus Type 1, Strain HTLV-III_B (HIV-1) (associated with AIDS) at 2 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 faecalis* (VRE), allow the treated surface to remain wet for 5 minutes.
- To disinfect against *Mycobacterium bovis* BCG (Tuberculosis), allow the treated surface to remain wet for 5 minutes.
- To disinfect against *Staphylococcus aureus* and Methicillin Resistant *Staphylococcus aureus* (MRSA), allow the treated surface to remain wet for 5 minutes.

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

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

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.

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.

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).

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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.

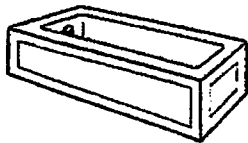
(Optional for Product Supplied in Single Use Pouches/Packets)

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

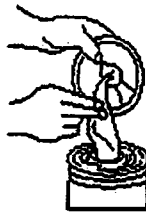
(Optional for Product Supplied in plastic bags for use in Center Pull Dispensers)

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.

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13



Bathtub



Canister Directions



Changing Table



Computer



Baby crib



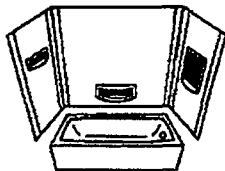
Door Knob



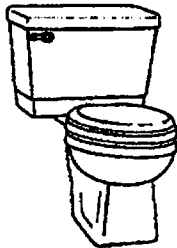
Faucet



Garbage Can



Tub and Shower walls



Toilet

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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	99.790%
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.