

69687-1

8/9/2011

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 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, DC 20460

AUG -9 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Paul Stiffler
 Medtrol, Inc.
 7157 North Austin Avenue
 Niles, IL 60714

Subject: PRIA (446728)
 Super-Chlor
 EPA Registration No. 69687-1
 Application Date: March 11, 2011
 EPA Receipt Date: March 14, 2011

Dear Mr. Stiffler:

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

Proposed Amendment:

- To comply with PR Notice 2007-4
- Remove *Mycobacterium bovis* from the label
- Add claims for Hepatitis B Virus (HBV)

Conditions:

1. Revise the "Hazards to Humans and Domestic Animals" statement as follows:

CAUTION: Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

2. Add the following statement under the "First Aid" section of the label: Have the product container with you when calling a poison control center or doctor, or going for treatment.
3. Identify the types of surfaces on which the product may be used (e.g., chrome, glass, stainless steel)

General Comments:

Should you wish to add/retain a reference to the company's website on your label, than please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. 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) list examples of statements EPA may

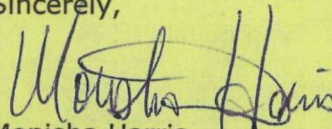
CONCURRENCES	
SYMBOL	75100
SURNAME	Lenison
DATE	8-9-11

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. 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 Compliance Assurance

A stamped copy of the labeling accepted with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact Wanda Henson on (703) 308-6345 or at Henson.Wanda@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Monisha Harris", is written over a horizontal line.

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Premoistened [3" x 3"] [3" x 4"] [5" x 9"] [6" x 6"] [6" x 7"] [6" x 8"] [6" x 9"] [7" x 9"] [8" x 10"] [9" x 6"] [9" x 12"] [14" x 14"]
Towelette
[CAT#SC110]

SUPER-CHLOR®[Product Name]

[For wiping] [Disinfecting wipe for] hard non-porous [surfaces] [environmental surfaces]
[and] [patient care equipment] [point-of-care equipment]
[+Virucidal] [for] [Hepatitis B Virus, [HBV]], [Human Immunodeficiency Virus Type 1, [+HIV-1]], [Fungicidal] [*Trichophyton mentagrophytes*] [ATCC 9533], [Bactericidal] [for] [*Staphylococcus aureus*-MRSA] [ATCC 33592], [*Enterococcus faecalis*-VRE] [ATCC 51575], [*Staphylococcus aureus*] [ATCC 6538], [*Salmonella enterica*] [ATCC 10708], and [*Pseudomonas aeruginosa*] [ATCC 15442]

Active Ingredient: Sodium hypochlorite.....0.525%
Other Ingredients*:99.475%
Total.....100.000%
*Other ingredients do not include the weight of towelette.

SUGGESTED AREAS OF USAGE:
[Medical] [.] [and] [Dental] [and] [Laboratory] [Counters] [.] [Exam Tables] [.] [Carts] [.] [Patient Care Equipment] [Point-of-Care Equipment] [.]
[Telephones] [.] [Sink Tops] [.] [Toilet Seats]

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID: If in eyes: Hold eye 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 eye. Call a poison control center or doctor for treatment advice.

(See [side] [back] panel[s] [on reverse] for directions for use and additional precautionary statements.)

EPA Reg. No. 69687-1
EPA Est. No. 69687-IL-001

[MEDTROL logo]
[©2004 Medtrol, Inc.]
Net Contents [0.1][0.15][0.2][0.25][0.3]
[0.4][0.5][0.6][0.7][0.8][0.9][1.0] oz.
U.S. Patent No. 6,530,477
[DIN: {insert # as applicable}]

{Administrative Note: Bracketed text [] is optional version of text for different packaging.}
{Administrative Note: The terms "towelette(s)", "towel(s)", "wipe(s)", "wiper(s)" and "cloth(s)" and the terms "Premoistened", "Premeasured", "Convenient", "Disposable" and "Pre-saturated" may be used interchangeably throughout.}

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG -9 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 69687-1

Directions for use:

- It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
- Always use personal protective equipment.
- Thoroughly clean gross filth and heavy soil from surfaces prior to disinfection.
- Open [Super-Chlor®][Product name] [packet] [canister].
- Remove premoistened [3" x 3"][3" x 4"][5" x 9"][6" x 6"][6" x 7"][6" x 8"][9" x 9"][12" x 12"] [14" x 14"] towelette.
- Apply towelette and wipe desired surface to be [decontaminated][disinfected].
- A 5 minute contact time is required for effectiveness against organisms listed. Allow treated surfaces to remain thoroughly wet for 5 minutes.
- Allow surface to air dry and discard [used] towelette and [empty] [packet][canister] (see storage/disposal).

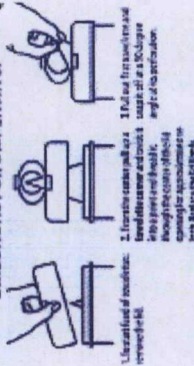
{Optional text for use with canister offerings}

[To open canister:

- Remove lid from canister
- Lift flap in canister lid
- Pull up corner of center towelette/wipe and snap off, twist to a point and thread through dispenser hole in lid.
- DO NOT PUSH FINGER THROUGH OPENING
- Replace lid. Pull out exposed towelette/wipe and snap off. The next towelette/wipe pops up automatically.
- Dispose of used towelette/wipe in trash receptacle.
- Snap center flap down when finished to retain moisture.
- Do not flush towelette/wipe into toilet.

{Optional text for use with canister}

DIRECTIONS FOR DISPENSING:



{Optional text for single use packet}

[TO OPEN PACKAGE: Tear open (along dotted line) (at tear notch) (along the top edge of pouch). (Pull out) (Remove) towelette.

[Unfold towelette before use.] Dispose used wipes/towelette in trash. Do not flush wipes/towelette into toilet. Discard used wipes [towelette] and empty packet in designated infectious waste container for disposal according to Federal, State and Local regulations.

{Administrative Note: If a virucidal and/or HIV claim is made the following paragraph and special instructions are required}

+KILLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of HIV-1 (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

- PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable [protective] [latex] gloves, gown, masks and eye protection.
- CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of [Super-Chlor][Product Name].

- **CONTACT TIME:** Allow surface to remain wet for 5 minutes.
- **DISPOSAL OF INFECTIOUS MATERIAL:** Blood/body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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.

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 barriers or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Keep this product (wipe/towelette) in a tightly closed container/canister when not in use. Store canister in cool, dry and well-ventilated area away from heat, open flame, direct sunlight and inaccessible to children. In case of spill, isolate container (if possible) and flood area with large amounts of water to dissolve all material before discarding this container in trash.

Pesticide (towelette/wipe) Disposal: Towelette/wipe wastes are acutely hazardous. Improper disposal of excess towelette/wipe is a violation of Federal Law. Dispose of wipe/towelette in trash after use. Do not flush wipe/towelette into the toilet. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the EPA Regional Office for guidance.

Container/Canister Handling and Disposal:

A. [For Household/Residential Products]

[For rigid non-refillable container/canister less than 5 gallons]

Container Handling: Non-refillable rigid container/canister. Do not re-use or refill this container/canister. Triple rinse (or equivalent), promptly after emptying. Offer for recycling, if available, or throw in trash.

B. [For Commercial/Industrial/Institutional Products]

[For rigid non-refillable container/canister less than 5 gallons]

Container Handling: Non-refillable rigid container/canister. Do not re-use or refill this container/canister. Triple rinse (or equivalent), promptly after emptying. Offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay away of smoke.

Complete product line information available by calling:

7157 North Austin Avenue
Niles, Illinois 60714
Ph: 800-647-7180 Fx: 800-255-3027

[MEDTROL, INC. logo]

e-mail: sales@medtrol.com
Website: www.medtrol.com
[BARCODE LABEL]

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{OPTIONAL ADDITIONAL TEXT FOR USE ON PRODUCT LABEL OR COLLATERAL LABELING}

[[Effective against] [Kills] hospital [type] [representative] bacteria
Staphylococcus aureus [ATCC 6538], Salmonella enterica [ATCC 10708], and
Pseudomonas aeruginosa [ATCC 15442]]

[[Effective against] [Kills] Hepatitis B Virus [in 30 seconds] [in 30 sec.] [in the
presence of organic soil (5% blood serum)]]

[[Effective against] [Kills] HBV [in 30 seconds] [in 30 sec.] [in the presence of
organic soil (5% blood serum)]]

[[Effective against] [Kills] Trichophyton mentagrophytes [ATCC 9533]]

[[Effective against] [Kills] Methicillin Resistant Staphylococcus aureus
(MRSA) [ATCC 33592]]

[[Effective against] [Kills] Enterococcus faecalis (VRE) [ATCC 51575]]

[[Effective against] [Kills] Staphylococcus aureus and Salmonella enterica]

[A One Step Cleaner Disinfectant effective against: [Pseudomonas
aeruginosa] [Staphylococcus aureus] [Salmonella enterica] [Methicillin
Resistant Staphylococcus aureus (MRSA)] [Vancomycin Resistant
Enterococcus faecalis (VRE)] [in the presence of organic soil (5% blood
serum)]]

[Where control of the hazards of cross contamination between treated
surfaces is of prime importance]

[Antibacterial]

[Aids in reducing [in the reduction of] cross contamination between treated
surfaces]

[An effective method to disinfect hard, non-porous environmental surfaces]

[[Use to] [Effectively] [cleans and] disinfects common hard, non-porous
surfaces]

[An effective way to clean and deodorize against odor-causing organisms
and disinfect hard, non-porous surfaces]

[Can be used to][Clean][s] [,][deodorize][s] and disinfect][s]

[Optional symbol] [Not A Baby Wipe]

[In the][area] [center] [station][department][s][listed][below][here][:]
[Hospitals][Doctors's Offices][Nursing Homes][Schools] [Dental Offices]
[Environmental Services][Renal Dialysis][Laboratories][Infection Control]
[ICU/CCU][General Nursing] {Nursing}[Home Healthcare] Pediatrics] {Out
Patient Care] [Surgery][Respiratory Care][EMS][Housekeeping]

[Expiration date] [EXP] [XXXXXX]

{OPTIONAL ADDITIONAL TEXT FOR USE ON PRODUCT LABEL OR COLLATERAL LABELING}

[Can be used on hard non-porous surfaces of] [blood glucose meters] [blood glucose monitors] [stethoscopes] [in blood glucose meter rental programs]

Made in U.S.A

[Innovative healthcare product designed with a commitment to quality and excellence]

[For complete product line information, Call Medtrol, Inc.]

[Complete product line information available by calling:]

[[Effective against] [Kills] [and] [the] *HIV-1 (AIDS Virus) [and] on precleaned hard non-porous environmental surfaces]

[[Effective against] [Kills] [and] [the] HBV [and] on precleaned hard non-porous environmental surfaces]

[[Effective against] [Kills] [and] [the] Hepatitis B Virus [and] on precleaned hard non-porous environmental surfaces]

[Can be used to][Disinfect[s] hard, non-porous [environmental] [healthcare] surfaces]

[Bathroom [disinfectant] wipes for hard, non-porous environmental surfaces]

[Use wipes to kill [Salmonella enterica (Salmonella)] [and] [Staphylococcus aureus (Staph)] on bathroom hard, non-porous surfaces]

[Can be used on][[Telephone][s]][[cell] [cellular] [wireless] [mobile] [digital] phone[s]] [disinfectant wipe]

[Can be used to][Disinfect[s] [headsets] [telephones] [[cell] [cellular] [wireless] [mobile] [digital] phone[s]]

[Ready to Use]

[Contains 5,250 [parts per million] [ppm] of active sodium hypochlorite]

[[Convenient] [Premeasured] [Premoistened] [Disposable] [Pre-saturated] [towelette]

[No mixing] [No measuring]

[Moist inanimate surface wipes]

{OPTIONAL ADDITIONAL TEXT FOR USE ON PRODUCT LABEL OR COLLATERAL LABELING}

[Can be used on][Use on hard][,] non-porous surfaces only.]

[Test wipe on small inconspicuous area.]

[Suitable for hospital use]

[Disinfects hard, non-porous healthcare surfaces]