

09687-1

11/21/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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Washington, D.C. 20460

November 21, 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Bob MacDonald
Agent for Medtrol, Inc.
c/o SRC Scientific & Regulatory Consultants
P.O. Box 1014
Columbia City, IN 46725

Subject: Super-Chlor
EPA Registration No. 69687-1
Application Date: August 20, 2008
Receipt Date: August 25, 2008

Dear Mr. MacDonald:

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

- Revise label pursuant to Agency letter dated 11/25/07
- Add optional descriptor term "protective" for disposable gloves

General Comments

A stamped copy of the accepted labeling 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 or comments concerning this letter, please contact Wanda Henson at 703-308-6345.

Sincerely,

Emily H. Mitchell
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

MBOL	7510P	7510P						
IRNAME	EKB-19	E. Mitchell						
ATE	11/21/08	11/21/08						

Premoistened [3" x 3"] [3" x 4"] [8" x 10"] [9" x 9"] [12" 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]

[Tuberculocidal] [*Mycobacterium bovis* – BCG (OT451C150)] [*Mycobacterium bovis* variant tuberculosis] [OT 451C150] [(Tuberculosis)] [(TB)]
[+Virucidal] [+HIV-I], [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.

STORAGE AND DISPOSAL

- Store product in a cool, dry area, away from heat and direct sunlight. • Do not reuse empty packet and used towelette. • Discard used towelette and empty packet in designated infectious waste container for autoclaving and disposal according to federal, state and local regulations.

(See panel on reverse for directions for use and additional precautionary statements.)

EPA Reg. No. 69687-1

EPA Est. No. 69687-IL-001

[MEDTROL logo]

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Net Contents [0.1][0.15][0.2][0.25]

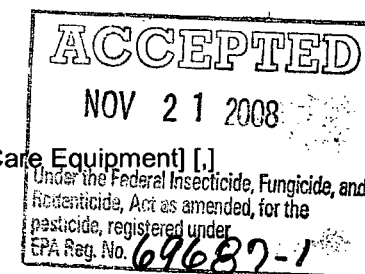
[0.3][0.4][0.5][0.6][0.7][0.8] fl. oz.

U.S. Patent No. 6,530,477,B1

[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)" may be used interchangeably throughout.}



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.
- Gross filth and heavy soil should be removed prior to disinfection.
- Open [Super-Chlor™][Product name] packet.
- Remove premoistened [3" x 3"] [3" x 4"] [8" X 10"] [9" x 9"] [12" x 12"] [14" x 14"] towelette.
- Apply towelette and wipe desired surface to be [decontaminated][disinfected].
- A 5 minute contact is required for effectiveness against organisms listed.
- Allow surface to air dry and discard used towelette and empty packet (see front panel).

{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 or 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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]

{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)", may be used interchangeably throughout.}

{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] Mycobacterium bovis variant tuberculosis [OT 451C150]]

[[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)]

[[Effective against] [Kills] Mycobacterium bovis variant tuberculosis [OT 451C150] [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]

[Cleans [,][deodorizes] and disinfects]

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

**[[Effective against] [Kills] Mycobacterium bovis – BCG (OT 451C150) [in the
presence of organic soil (5% blood serum)]**

**[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) on precleaned hard non-
porous environmental surfaces]**

[Disinfects 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]**

**[[Telephone] [[cell] [cellular] [wireless] [mobile] [digital] phone[s]] disinfectant
wipe]**

**[Disinfects [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] towelette]

[No mixing] [No measuring]

[Moist inanimate surface wipes]

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

[Test wipe on small inconspicuous area.]

[Suitable for hospital use]

[Disinfects hard, non-porous healthcare surfaces]