

69687-1

08/30/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 30 2004

Mr. Bob MacDonald
Medtrol Inc.
7157 Austin Avenue
Niles, IL 60714

Subject: Super-Chlor™
EPA Registration Number 69687-1
Application Date: 6/18/03
Receipt Date: 6/20/03

Dear Mr. MacDonald:

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:

- To add additional claims

Conditions

- In accordance with DSS/TSS-15 requirements, you must revise the "Directions for Use" section of the proposed label to include the following:
 - A statement indicating that heavily soiled areas should be pre-cleaned prior to disinfecting.
 - The contact time necessary for effectiveness as a disinfectant. The "Special Instructions" section for cleaning against HIV-1 specifies a contact time of 10 minutes. No other contact times are identified on the proposed label.
- The proposed label claims that the towelette product, Super-Chlor, is an effective disinfectant against the following microorganisms when used in the presence of a 5% organic soil load: **Enterococcus faecalis - VRE, Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus , and Staphylococcus aureus - MRSA.**

These claims are supported by your data; however, you must revise the "Directions for Use" section to include a 5 minute contact time.

CONCURRENCES							
SYMBOL		2516					
SURNAME		E. Mitchell					
DATE		8-30-04					

3. The proposed label claims that the towelette product, Super-Chlor, is an effective disinfectant against the following Microorganisms: **Trichophyton mentagrophytes** and **HIV-1**.

These claims are supported by your data; however, you must revise the "Directions for Use" section to include a 5 minute contact time. Note that the "Special Instructions" section for cleaning against HIV-1 specifies a contact time of 10 minutes even though the product was demonstrated to be effective against HIV-1 at a 5 minute contact time.

4. The proposed label claims that the product, Super-Chlor, is an effective disinfectant against **Mycobacterium bovis - BGG** when used in the presence of a 5% organic soil load.

These claims are supported by your data; however, you must revise the "Directions for Use" section to include a 5 minute contact time.

5. The proposed label includes optional text that indicates that the product, Super-Chlor, is effective against common household bacteria (see page 3 of the proposed label, last item). The product is not being marketed for use in household environments; therefore, delete this text from the proposed label.

6. Make the following changes:

- On page 3 of the proposed label [2nd item], change "Mycobaterium" to read "Mycobacterium".
- On page 3 of the proposed label [6th item], change "cholerasuis" to read "choleraesuis".
- On page 3 of the proposed label [7th item], change "auruginosa" to read "aeruginosa".
- On page 3 of the proposed label [7th item], change "faecalise" to read "faecalis".
- On page 4 of the proposed label [2nd item], change "quaulity" to read "quality".
- On page 4 of the proposed label [8th item], change "cholerasuis" to read "choleraesuis".

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 Delores Williams at (703) 308-6372.

Sincerely,

Emily Mitchell
Acting Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

[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]

ACCEPTED
with COMMENTS
EPA Letter Dated:

Other Ingredients*:99.475%

*Other ingredients do not include the weight of towelette.

AUG 30 2004

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

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

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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.

- ♦ 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.)

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.}

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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.
- 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].
- 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 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 10 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.}

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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 choleraesuis [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 choleraesuis]

[A One Step Cleaner Disinfectant effective against: [Pseudomonas aeruginosa] [Staphylococcus aureus] [Salmonella choleraesuis] [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]

~~[[Effective against] [Kills] common household bacteria]~~

**{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 quaulity 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 cholerasuis (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]