

WASHINGTON, D.C. 20460

United States
Environmental Protection
Agency**Office of Pesticide Programs**

January 13, 2009

Bob MacDonald
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

FILE COPY

Subject: Medtrol, Inc.
Super-Chlor
EPA Reg. No.: 69687-1
Application Dated: December 24, 2008
Receipt Dated: December 30, 2008

Dear Mr. MacDonald:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA Section 3(c)9.

Notification

- Interchangeable use of the terms: Convenient, Premeasured, Disposal, and Pre-moistened
- Providing [0.9][1.0] oz. in Net Content
- Add the following descriptors identified by parenthesis: "Allow surface to air dry and discard (used) towelette and (empty) packet."

General Comments

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

This 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 me at (703) 308-6345.

Sincerely,

Wanda Henson
Product Reviewer - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 69687-1	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Super-Chlor	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Medtrol, Inc. 7157 Austin Avenue Niles, IL 60714 <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: 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.)

Notification through PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please forward any questions to the attention of Bob MacDonald at Scientific & Regulatory Consultants, Inc. (by e-mail) at bmacdonald@srcconsultants.com or fax) (260) 244-6273.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.1, 0.15, 0.2, 0.25, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 2.0		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input 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 Bob MacDonald		Title Agent for Medtrol Inc.	
		Telephone No. (Include Area Code) 260-244-6270	
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 		3. Title Agent for Medtrol Inc.	
4. Typed Name Bob MacDonald		5. Date 12/24/08	

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SRC

Scientific & Regulatory

Consultants, Inc.

December 24, 2008

Ms. Emily Mitchell, PM 32
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: Super-Chlor EPA Reg. No. 69687-1

Dear Emily,

On behalf of our client, Medtrol, Inc., enclosed is a notification to request the listing of optional descriptive text for their offering in the Administrative Notes, the designation of "used" and "empty" as being optional text and the inclusion of Non-Notification Net Contents changes due to recent State requirements to declare weight oz. as opposed to fl. oz.

The Master Label's front panel currently states:

"Premoistened [3" x 3"] [3" x 4"] [8" x 10"] [9" x 9"] [12" x 12"] [14" x 14"] Towelette"

Their optional text pages have gained acceptance and previous clearance of:

[[Convenient] [Premeasured] [Premoistened] [Disposable] towelette]

Our client wishes to note on the Master Label that these terms along with "Pre-saturated" may be used interchangeably and have so noted this in the Administrative Notes as done for towelette(s) etc.

On the back panel of labeling and in the last "Directions for use" statement we wish to make "used" before towelette and "empty" before packet as optional since these descriptors are not necessary and reduce the text required for small package offerings.

Finally we are reflecting the Net Contents in weight oz. and although this can be accomplished by non notification we are including this with their submission to officially update the Master Label on this declaration.

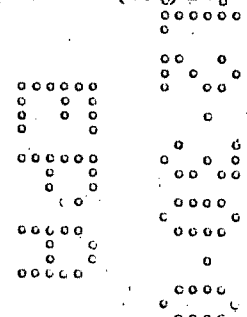
We have enclosed two copies of the labeling. One with a simply highlight of the change and one with the change "circled" so it may be copied. Otherwise the labeling is consistent with the most recently accepted stamped label.

Thank you for your assistance on this matter. If you have any questions please contact me at (260) 244-6270 or by e-mail at bmacdonald@srcconsultants.com.

Sincerely



Bob MacDonald
Agent for Medtrol, Inc.



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]

©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,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)" and the terms "Premoistened", "Premeasured", "Convenient", "Disposable" and "Pre-saturated" 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)" and the terms "Premoistened", "Premeasured", "Convenient", "Disposable" and "Pre-saturated" 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 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]

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**{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] [Pre-saturated]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]