

69687-1

01-18-2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 18, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Heather R. Bjornson, Consultant
Technology Sciences Group, Inc
1150 18th Street, NW, Suite 1000
Washington, DC 20036

Subject: Super-Chlor
EPA Reg.#: 69687-1
Notification Date: December 20, 2012
Receipt Date: December 22, 2012

Dear Ms. Bjornson:

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

Proposed Notification:

To make minor text label revisions on the master text label for "Super-Chlor" (EPA Reg# 69687-1). Master label dated December 20, 2011.

General Comment:

Based on the review of the material submitted, the notification application for minor text revisions to the master label (dated December 20, 2011) for "Super-Chlor" (EPA Reg# 69687-1), is acceptable.

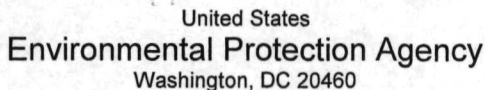
This notification and this letter have been inserted in your file for future reference.

If you have further question on this letter, please contact David Liem at 703-305-1284 or by email at liem.david@epa.gov

Sincerely

A handwritten signature in black ink, appearing to read "Monisha Henson", is written over a circular stamp or seal.

Monisha Henson
Product Manager (PM 32)
Regulatory Management Branch II
Antimicrobial Division (7510P)



☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

1. Company/Product Number 69687-1	2. EPA Product Manager Monisha Harris	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name) Super- Chlor	PM# 32	
5. Name And Address Of Applicant (Include ZIP Code) Medtrol, Inc. 7157 North Austin Avenue Niles, Illinois 60714 ☐ 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 _____	

☐ Amendment – Explain below.
 ☐ Resubmission in response to Agency letter dated _____
 ☐ Final Printed labels in response to Agency letter dated _____

☒ Notification – Explain below.
 ☐ "Me Too" Application.
 ☐ Other – Explain Below.

This notification is to make minor text revisions.

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 the confidential statement of formula for 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.

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging ☐ Yes* ☒ No	Unit Packaging ☒ Yes ☐ No	Water Soluble Packaging ☐ Yes ☒ No	2. Type of Container ☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) _____
	If "Yes" Unit Packaging wgt.	No. per Container	
3. Location of Net Contents Information ☒ Label ☐ Container		4. Size(S) Retail Container	
6. Manner in Which Label is Affixed to Product		5. Location of Label Directions ☒ On Label ☐ On Labeling accompanying product	
		☒ Lithographed ☒ Paper glued ☐ Stenciled	
		☐ Other _____	

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8945
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 Regulatory Consultant to Medtrol, Inc.	
4. Typed Name Heather R. Bjornson	5. Date December 20, 2011	

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

SUPER-CHLOR® [Product Name]

[For wiping] [Disinfecting wipe for] hard [,] non-porous [surfaces] [environmental surfaces]
[&][and] [patient care equipment] [,] [and] [point-of-care equipment][,]

[Effective against] [Kills] [Virucidal] [for] [Hepatitis B Virus,] [HBV,] [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], [Digital screens] [on] [Plastics] [Glazed Porcelain] [Stainless Steel] [Formica] [Vinyl] [and] [Rubber
Surfaces]

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.

Have the product container with you when calling a poison control center or doctor, or going for treatment.

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

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EPA Est. No. 69687-IL-001

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.
[DIN: {insert # as applicable}]

[MEDTROL logo]
[©2004 Medtrol, Inc.]

{Administrative Note: Bracketed text [] is optional version of text for different packaging.}

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{Administrative Note: The terms "towelette(s)", "towel(s)", "wipe(s)", "wiper(s)" and "cloth(s)" and the terms "Premoistened", "Premeasured", "Convenient", "Disposable", "Disposible" and "Pre-saturated" may be used interchangeably throughout.}

DIRECTIONS FOR USE

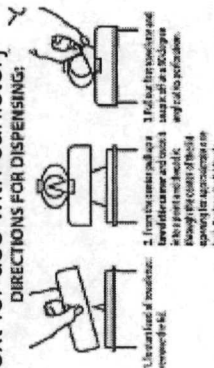
- It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
- Always use personal protective equipment.
- Thoroughly clean gross filth and heavy soil from surfaces prior to disinfection.
- Open [Super-Chlor®][Product name] [packet] [canister].
- Remove premoistened [3" x 3"] [3" x 4"] [5" x 9"] [6" x 7"] [6" x 8"] [7" x 9"] [7" x 8"] [7" x 9"] [8" x 7"] [8" x 9"] [8" x 10"] [9" x 6"] [9" x 9"] [12" x 14"] [14" x 14"] towelette.
- Apply towelette and wipe desired surface to be [decontaminated][disinfected].
- (Note: one of the two statements will be on the label.) [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 and 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.
- Snap center flap down when finished to retain moisture.
- Do not flush towelette/wipe into toilet.]

{Optional text for use with canister}



[Optional text for refills sold separately]

- To refill the wipes [towelette] cut open sealed pouch and place [the roll of wipes] into the canister.
- 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.

- Snap center flap down when finished to retain moisture.
- Do not flush towelette/wipe into toilet.]

{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 [towellette] 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 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.

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.

STORAGE AND DISPOSAL

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

Pesticide Storage: [For product sold in canisters] 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. . [For product sold in individual packets] Store in a cool, dry, and well-ventilated area away from heat, open flame, direct sunlight and inaccessible to children.

Pesticide (towelette/wipe) Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides 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 nonrefillable container/canister less than 5 gallons]

Container Handling: Nonrefillable 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 nonrefillable container/canister less than 5 gallons]

Container Handling: Nonrefillable rigid container/canister. Do not re-use or refill this container. 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 out of smoke.

C. [For Refillable Containers]

Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. To clean the container before final disposal; 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 out of smoke.

D. For individual packed wipes [towelettes]

Container Handling: Wipes: Dispose of [wipe] [towelette] in trash after use. Do not flush. Offer empty packet for recycling if available or discard in trash.

Complete product line information available by calling:

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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 "towellette(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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[illegible]
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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 [HBV] [in 30 seconds] [in 30 sec.]
[in the presence of organic soil (5% blood serum)] [and] [on [precleaned]
hard, non-porous [environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] [Human Immunodeficiency Virus Type 1] [HIV-1] [in
30 seconds] [in 30 sec.] [in presence of organic soil (5% blood serum)] [and]
[on [precleaned] hard, non-porous [environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] Trichophyton mentagrophytes [ATCC 9533]] [in
presence of organic soil (5% blood serum)] [and] [on [precleaned] hard, non-
porous [environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] Methicillin Resistant Staphylococcus aureus
[MRSA] [ATCC 33592]] [in presence of organic soil (5% blood serum)] [and]
[on [precleaned] hard, non-porous [environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] [Vancomycin Resistant Enterococcus faecalis
[VRE] [ATCC 51575]] [in presence of organic soil (5% blood serum)] [and] [on
[precleaned] hard, non-porous [environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] [Staphylococcus aureus] [S. aureus] [ATCC 6538]
and Salmonella enterica] [in presence of organic soil (5% blood serum)] [and]
[on [precleaned] hard, non-porous [environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] [Salmonella enterica] [ATCC 107108] [in presence
of organic soil (5% blood serum)] [and] [on [precleaned] hard, non-porous
[environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] [Pseudomonas aeruginosa] [ATCC 15442] [in
presence of organic soil (5% blood serum)] [and] [on [precleaned] hard, non-
porous [environmental]][and][healthcare] surfaces]

[[Effective against] [Kills] Staphylococcus aureus [ATCC 6538], Salmonella
enterica] [ATCC 107108] and Pseudomonas aeruginosa [ATCC 15442]

[A One Step Cleaner Disinfectant effective against: [Pseudomonas
aeruginosa] [Staphylococcus aureus] [Salmonella enterica] [Methicillin
Resistant Staphylococcus aureus (MRSA)] [Vancomycin Resistant

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Enterococcus faecalis (VRE)] [Hepatitis B Virus] [HBV] [Human Immunodeficiency Virus Type 1] [HIV-1] [Trichophyton mentagrophytes] [in the presence of organic soil (5% blood serum)] [and]] [on [precleaned] hard, non-porous [environmental]] [and] [healthcare] surfaces

[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] [EXP DATE] [XXXXXX]

[Lot Numbe] [Lot] {xxxxxx}

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

Made in [the] 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:]

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

[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]

[Refills for [Product Name]

[For refilling [Product Name]

[germicidal wipes]

[germicidal] [germicide]

[bleach [(sodium hypochlorite)] disinfectant wipe]

[1:10 bleach [(sodium hypochlorite)] [dilution] [solution]]

[sodium hypochlorite 0.525%]

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[[Product Name][These][The][towels] are saturated with [the] a solution
[equivalent to] [of] [prediluted] 1;10 [dilution of] sodium hypochlorite [bleach]]

[meets efficacy standards for hospital disinfection]

[bleach disinfectants][1:10 dilution] [hospital use]

[presaturated] [towel] [towelette] [wipe]