

69687-1

8/6/2012

1/13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

August 6 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Abigail T Downs
Regulatory Agent to MedTrol Inc
1150 18th Street NW Suite 1000
Washington DC 20036

Subject Super Chlor®
EPA Reg # 69687 1
Notification Date July 12 2012
Receipt Date July 12 2012

Dear Ms Downs

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 add optional label claims (Single use Only Protect from freezing Avoid excessive heat and Shield from direct sunlight) for Super Chlor® (EPA Reg # 69687 1) Submitted label pin punched 07/25/12

General Comment

Based on the review of the material submitted this notification to add optional label claims is acceptable

It is noted that changes were also made in response to the Agency s amendment comments dated May 16, 2012 into the current submitted label (Label amendment dated February 16 2012 and pin punch 7/25/12)

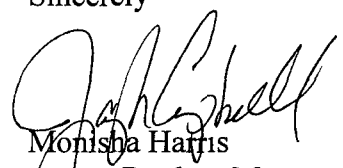
On page 4 of the current label it was noted a website addition www.medtrol.com Should you wish to retain a reference to the company's website on your label then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency If the website content is false or misleading the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E) 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

Although EPA has not yet determined the extent to which it will routinely review company websites if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process the website may be referred to the EPA's Office of Enforcement and Compliance Assurance

This notification and a copy of this letter have been inserted in your file for future reference

If you have any questions on this letter please contact David Liem at 703 305 1284 or by email at liem.david@epa.gov

Sincerely



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



United States
Environmental Protection Agency
Washington DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide Section I

1 Company/Product Number 69687 1	2 EPA Product Manager Monisha Harris	3 Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4 Company/Product (Name) Medtrol Inc / Super Chlor	PM# 32	
5 Name and Address of Applicant (Include ZIP Code) Medtrol Inc 7157 Autsin 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 to add additional optional label claims
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 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

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	If Yes Unit Packaging wgt No per container		<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 Package wgt No per container			
3 Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4 Size(s) Retail Container	5 Location of Label Directions []			
6 Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued 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 Abigail Downs	Title Regulatory Consultant	Telephone No (Include Area Code) 202 828 8992
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 Agent to Medtrol Inc	
4 Typed Name Abigail T Downs	5 Date July 12, 2012	

4/13



Technology Sciences Group Inc

1150 18th Street NW Suite 1000
Washington D C 20036
Direct (202) 828 8992
Fax (202) 872 0745
E Mail adowns@tsgusa.com

Abigail T Downs
Regulatory Consultant

Monisha Harris
Office of Pesticide Products
U S Environmental Protection Agency
Room S 4900 One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202 4501

July 12 2012

Re Notification to Update Optional Label Claims
Company Name Medtrol Inc
Product Name Super Chlor
EPA Registration No 69687 1

Dear Ms Harris

Technology Sciences Group Inc on behalf Medtrol Inc is submitting the enclosed notification to add the following optional label claims to the Super Chlor product label

- Single Use Only
- Protect from freezing
- Avoid excessive heat
- Shield from direct sunlight

Please see the following included in support of this application

- 1) Amendment application form 8570 1

Please do not hesitate to contact me with any questions at (202) 828 8992 or via e mail adowns@tsgusa.com

Sincerely

Abigail T Downs

Premoistened [3 x 3][3 x 4][5 x 9][6 x 6][6 x 7][6 x 8][7 x 9][8 x 7][8 x 9][8 x 10][9 x 6][9 x 9][12 x 12][14 x 14] Towellette
[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] [[+Human Immunodeficiency Virus Type 1][+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] [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)

EPA Reg No 69687 1
EPA Est No 69687 IL 001

Net Contents [0 1][0 15][0 2][0 25][0 5]
[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 }

NOTIFICATION
Data Reviewed
Reviewed By 

5/13

{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

Hospital Disinfection

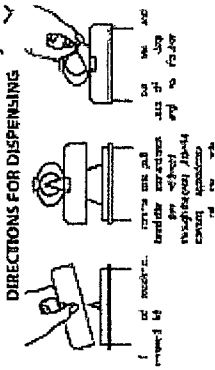
- Always use personal protective equipment
- Thoroughly clean gross filth and heavy soil from surfaces prior to disinfection
- Open [Super Chlor®][Product name] [packet] [canister]
- Remove premoistened [3 x 3][3 x 4][5 x 9][6 x 6 x 7][6 x 8 x 9][7 x 8][7 x 9] [8 x 7][8 x 9][8 X 10][9 x 6][9 x 9][12 x 12][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

6/13

- 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 [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 and HBV 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 and HBV (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 surfaces to remain wet for 30 seconds to kill HBV and 5 minutes to kill HIV and the other organisms listed on the label
- 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 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

7/13

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 Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

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 reuse 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 reuse 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

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]

Label amendment dated February 16, 2012
Page 4 of 9

8/13

{Administrative Note Bracketed text [] is optional version of text for different packaging }
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Convenient Disposable and Pre saturated may be used interchangeably throughout }

9/13

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

[[Effective against] [Kills] 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 5 minutes [in 5 min] [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 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]

[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%]

[[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]

[Bleach wipes]

[Now Kills] *(note to reviewer to be used with hepatitis B claim – limited to 6 months of marketing)*

[Now effective against] *(note to reviewer to be used with hepatitis B claim – limited to 6 months of marketing)*

[Disinfectant] [Disinfecting] bleach wipe[s]

Disinfects [blood glucose meters] [] [and] [patient care equipment] [,] [and] [point of care equipment] and hard, non porous healthcare surfaces]

[Not a skin wipe] [] (pictogram)

[Not a baby wipe] [] (pictogram)

Single Use Only

Protect from freezing

Avoid excessive heat

Shield from direct sunlight