

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

69687-2

12/29/2006

Page 185

December 29, 2006

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

Subject: Chloro-Sol
EPA Registration No. 69687-2
Application Date: December 6, 2006
Receipt Date: December 13, 2006

Dear Mr. MacDonald:

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

Proposed Notification

- Addition of "Total" line to ingredient statement

General Comments

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

The notification application is acceptable and a copy has been placed 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 Y. Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

		CONCURRENCES					
SYMBOL	7510P	7510P					
IRNAME	E. Berg	E. Yritcho					
DATE	12/29/06	1/3/07					



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 69687-2	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Chloro-Sol	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@srconsultants.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		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 12/16/98	

SRC
Scientific & Regulatory
Consultants, Inc.

December 12, 2006

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: NOTIFICATION
Chloro-Sol
EPA Reg. No. 69687-2

Dear Emily,

On behalf of our client, Medtrol, Inc., enclosed is a notification to official update their ingredient statement for the above product to include the standard "Total ...100%" declaration. We are resubmitting this notification per the recent response from Wanda Henson dated 11/28/06 (copy enclosed) requesting a complete label for this notification.

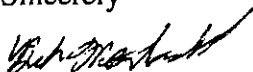
Their updated declaration includes the "Total" line and appears as follows:

Active Ingredient: Sodium hypochlorite	0.525%
Other Ingredients:.....	99.475%
Total.....	100.000%

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.

CHLORO-SOL™ [Product Name]

For [Cleaning] [,] [Sanitization] [and] [Decontamination] [of] Hard Non-Porous [Surfaces] [Environmental Surfaces] [/] [,] [Patient Care Equipment Surfaces] Soiled with Blood & Body Fluids Prior to High Level Disinfectant and Sterilization.

Active Ingredient: Sodium hypochlorite..... 0.525%
Other Ingredients:99.475%
Total.....100.000%

SUGGESTED AREAS OF USAGE:

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

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. 69687-2
EPA Est. No. 69687-IL-001

[MEDTROL, INC. logo]
[© 2004 Medtrol, Inc.]

[DIN: 02246210]
Net Contents [1 fl. oz.]
[16 fl. oz.]
[32 fl. oz.]

{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.}

{Administrative Note: The terms "packet(s)", "container(s)" and "bottle(s)" may be used interchangeably throughout.}

485

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 such as disposable gloves, gowns, masks or eye coverings when handling items soiled with blood and body fluids.
- Open [Chloro-Sol™] [Product Name] packet.
- [Pour] [Apply] [Spray] [Chloro-Sol] [Product Name] [liquid] [solution] on desired surface.
- Scrub and wipe with towel of your choice over desired surface to be [decontaminated] [disinfected].
- Allow a minimum contact time of 15 minutes and then allow to air dry.
- Discard towel and [empty] packet (see front panel).

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
e-mail: sales@medtrol.com
Website: www.medtrol.com

[MEDTROL, INC. LOGO]

Ph: 800-647-7180
Fx: 800-255-3027
[BARCODE LABEL]

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

{Administrative Note: The terms "towel(s)", "wipe(s)", "wiper(s)" and "cloth(s)" may be used interchangeably throughout.}

{Administrative Note: The terms "packet(s)", "container(s)" and "bottle(s)" may be used interchangeably throughout.}

525