

69687-2

10/18/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OCT 18 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION**FILE COPY**

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

Subject: Chloro-Sol  
EPA Registration No. 69687-2  
Application Date: August 2, 2010  
EPA Receipt Date: August 5, 2010

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.

**Proposed Amendment:**

- Label Amendment

**Conditions:**

A. This product is registered as a sanitizer and cleaner. Therefore, you must remove all disinfectant claims and revise the label as follows:

1. Delete statement "[An effective method to disinfect hard, non-porous environmental surfaces]"
2. Revise the statement "[[Use to][Effectively][cleans and] disinfects common hard, non-porous surfaces]" by deleting the phrase "...and] disinfects..."
3. Revise the statement "[An effective way to clean and deodorize against odor-causing organisms and disinfect hard, non-porous surfaces]" by deleting the phrase "...and disinfect hard, non-porous surfaces..."
4. Revise the statement "[Cleans [,][deodorizes] and disinfects]" by deleting the phrase "...and disinfects..."
5. Delete the statement "[Disinfects hard, non-porous [environmental][healthcare] surfaces]"

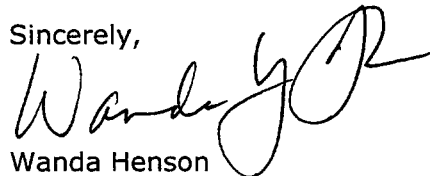
6. Revise the statement "[Suitable for hospital use][Hospital disinfectant]" by deleting the phrase "...[Hospital disinfectant]"
  7. Revise the statement "[Disinfecting][Bleach [Disinfecting] Solution][for hard, non-porous surfaces]" by deleting "Disinfecting" wherever it appears.
- B. Revise the Ingredient statement to change "Inert Ingredients" to "Other Ingredients."

**General Comments:**

A stamped copy of the accepted labeling is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact me at [Henson.Wanda@epa.gov](mailto:Henson.Wanda@epa.gov) or call (703) 308-6345.

Sincerely,

A handwritten signature in black ink, appearing to read "Wanda Henson", with a stylized flourish at the end.

Wanda Henson  
Acting Product Manager (32)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

[Prediluted Sodium hypochlorite [(Bleach)] Solution]

[CAT# CS114]

# 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].

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 18 2010

# KEEP OUT OF REACH OF CHILDREN CAUTION

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 69687-2

**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.}

**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](mailto:sales@medtrol.com)  
Website: [www.medtrol.com](http://www.medtrol.com)

[ MEDTROL, INC. LOGO ]

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

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

**[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]**

**[Innovative healthcare product designed with a commitment to quality and excellence]**

**[For complete product line information, Call Medtrol, Inc.]**

**[Disinfects hard, non-porous [environmental] [healthcare] surfaces]**

**[Ready to Use] [No mixing] [Convenient]**

**[Contains 5,250 [parts per million] [ppm] of active sodium hypochlorite]**

**[Use on hard, non-porous surfaces only.]**

**[Suitable for hospital use] [Hospital disinfectant]**

**[[Equivalent to] [Prediluted] 1:10 [dilution of] Sodium Hypochlorite [Bleach]][Solution]]**

**[X\* fl. oz. LIQUID BLEACH]**

**[[Disinfecting] [Bleach [Disinfecting] Solution] [for hard, non-porous surfaces]]**

\*{Administrative Note: X\* is replaced with 1, 16, 32 or any other future package size}  
{Administrative Note: Bracketed text [ ] is optional version of text for different packaging.}