

69687-2

12/26/2012

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

December 26, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Abigail T. Downs, Agent to Medtrol, Inc.
"TSG;" Technology Sciences Group, Inc.
1150 18th Street, NW
Suite 1000
Washington, DC 20036

Subject: Label Amendment Results
Product Name: **Chloro-Sol**
EPA Registration Number: **69687-2**
Application Date: December 18, 2012
Application Receipt: December 19, 2012

Dear Ms. Downs:

This acknowledges receipt of you Label Amendment application, submitted pursuant to registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 9, as amended.

Proposed Amendment:

Medtrol, Inc. is submitting the following labeling amendments for **EPA Reg. No. 69687-2:**

- 1.) Optional Marketing Claims; 2.) An update to the Precautionary Statement; 3.) An update to the Storage And Disposal Statement to comply with The Container Rule.

The submitted label was already approved when it was submitted as a Notification on December 3, 2012.

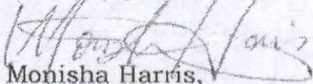
General Comments:

Based on the submitted material, the following comment applies. The Amendment application is Acceptable. A stamped, Accepted, Product Label is enclosed for your records. And a copy of this Agency Letter is attached in your file (**EPA Reg. No. 69687-2**) for future reference.

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If you have questions or comments with regard to this Agency Letter, please contact Killian Swift via email at Swift.Killian@epa.gov or by telephone at **703-308-6346**. When you are submitting information or data in response to this Agency Letter, please send a copy of this Agency Letter with your response in order to facilitate processing.

Sincerely yours,



Monisha Harris,
EPA Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped, **Accepted**, Chloro-Sol Product Label

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

CHLORO-SOL™ [Product Name]

For [Cleaning] [,] [Sanitization] [and] [Decontamination] [of] [Decontaminates] Hard Non-Porous [Surfaces] [Environmental Surfaces] [/] [,] [and] [Healthcare] [Surfaces] [on] [of] [/] [,] [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%

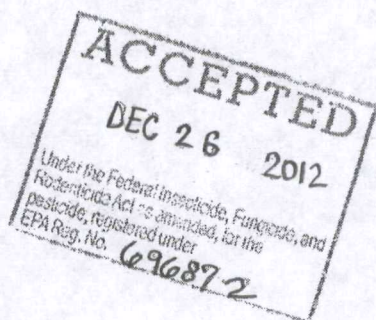
USE SITES:

[[Medical] [,] [Dental] [and] [Laboratory] Counters] [Countertops] [,] [Exam Tables] [,] [Carts] [,] [Point-of-Care Equipment Surfaces] [,] [Telephones] [,] [Sink Tops] [,] [Toilet Seats] [Patient Care Equipment] [,] [,] [and] [Digital Screens] [on] [Plastics] [,] [Porcelain] [,] [Stainless Steel] [,] [Formica] [,] [Vinyl] [,] [[and] [Rubber] [Surfaces]

KEEP OUT OF REACH OF CHILDREN

CAUTION

(See panel on reverse for directions for use and additional precautionary statements)



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FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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.	

EPA Reg. No. 69687-2
 [DIN: 02246210]
 EPA Est. No. 69687-IL-001
 Net Contents: [x fl. oz.]

[Medtrol, Inc. logo]
 [© 2012 Medtrol, Inc.]

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 and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

Physical and Chemical Hazards

This product contains bleach.

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] [container].
- [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 [used] towel and [empty] [packet][container] (see storage and disposal).

{One of the following statements MUST be used}

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.

Or

This product is not for use on critical or semi-critical medical device surfaces.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

PRODUCT DISPOSAL: Products or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer container for recycling. If recycling is not available, discard container in trash. After emptying container, fill with ¼ full of water and recap. Shake for 10 seconds and dispose rinsate in sanitary sewer.

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]

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

- All of the [raw materials] [components] of [this] [these] [liquid[s] [and] [canisters] [products] are made in the [U.S.A.] [USA]
- Assembled for [and distributed by] [Company Name]
- [Bleach solution] [prediluted sodium hypochlorite]
- Chloro-Sol [Product Name] is a Prediluted Bleach Solution for [sanitizing][decontaminating] hard, non-porous [surfaces] [environmental surfaces] [.]
- [Chloro-Sol] [Product Name] is [a] [a registered] [an EPA registered] [Prediluted sodium hypochlorite] [Bleach] [solution] [.]
- [Chloro-Sol] [Product Name] is a prediluted bleach solution for [sanitizing] [decontaminating] hard, non-porous [surfaces] [environmental surfaces] [.]
- Complete product line information available by calling: xxx-xxx-xxxx
- Sanitizes hard, non-porous [environmental] [healthcare] surfaces
- Distributed by [Company Name]
- [Expiration date] [EXP] [EXP DATE] [XXXXXX]
- For use in the [area] [center] [station] [department] [s] listed [below] [here] [:] [Hospitals] [Doscot's Offices] [Cursing Homes] [Schools] [Dental Offices] [Environmental Services] [Renal Dialysis] [Laboratories] [Infection Control] [ICU/CCU] [General Nursing] [Home Healthcare] [Pediatrics] [Out Patient Care] [Surgery] [Respiratory Care] [EMS] [Housekeeping]
- For use on hard non-porous surfaces.
- For use on [blood glucose meters] [blood glucose monitors] [stethoscopes].
- [Lot Number] [Lot XXXXXXXX]
- Made in U.S.A.
- Manufactured for [Company Name]
- [Manufactured] [and] [Distributed] [Sold] in the [USA] [U.S.A.]
- No Mixing] [No Measuring]
- Sodium Hypochlorite
- Sodium Hypochlorite [bleach] Solution
- Sold by [Company Name]
- Test on small inconspicuous area
- Use to [Effectively] [clean] [and sanitize] common hard, non-porous surfaces
- [Where control of the hazards of cross contamination between treated surfaces is of prime importance]

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- [Antibacterial]
- [Aids in reducing [in the reduction of] cross contamination between treated surfaces]
- [[Use to] [Effectively] [clean common hard, non-porous surfaces]
- [An effective way to clean against odor-causing organisms on hard, non-porous surfaces]
- [Cleans [,][deodorizes]
- [Innovative healthcare product designed with a commitment to quality and excellence]
- [For complete product line information, Call Medtrol, Inc.]
- [Ready to Use] [No mixing] [Convenient]
- [Contains 5,250 [parts per million] [ppm] of active sodium hypochlorite]
- [Use on hard, non-porous surfaces .]
- [Suitable for hospital use]
- [[Equivalent to] [Prediluted] 1:10 [dilution of] Sodium Hypochlorite [Bleach]][Solution]]
- [X* fl. oz. LIQUID BLEACH]