



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP - 9 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

SUBJECT: June 11, 2003 amendment
Chloro-Sol
EPA Registration 69687-2

Dear Mr. MacDonald:

The amendment referred to above, submitted in connection with registration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable with the following conditions. The words First Aid should be all caps and in larger type. Since you have removed the statement For Institutional and Commercial Use Only, you must provide Certification of Child Resistant Packaging in accordance with Part 157 Subpart B of the 40 CFR §157.22. You must submit this information along with a copy of your revised finished label for our files.

In summary, your request to revise the signal word to "Caution" and to list only treatment for accidental exposure to eyes is acceptable. A copy of your conditionally approved label is enclosed. If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,

Robert S. Brennis
Product Manager (32)
Regulatory Management Branch II
Antimicrobial Division (7510-C)

Enclosure

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

Prediluted Sodium hypochlorite (Bleach) Solution

CAT# CS114

CHLORO-SOL™

For Cleaning, Sanitization and Decontamination of 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%

SUGGESTED AREAS OF USAGE:

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

replace w/ FIRST AID:

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 towelette. ♦ Discard used towelette 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.)

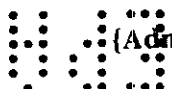
EPA Reg. No. 69687-2
EPA Est. No. 69687-IL-001



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

ACCEPTED
WITH COMMENTS
In EPA Letter Dated:
SEP -9 2003



(Administrative Note: Bracketed text [] is optional versions of text for different packaging)

CHLORO-SOL™
SODIUM HYPOCHLORITE
16 FL. OZ.
EPA Reg. No.

69687-2

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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™ packet]
- [Pour] [Apply] [Spray] [Chloro-Sol liquid] solution on desired surface
- Scrub and wipe with towel of your choice over desired surface to be decontaminated
- Allow a minimum contact time of 15 minutes and then allow to air dry
- Discard towel and 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 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:

7167 N. Austin Avenue
Miles, Illinois 60714
Website: www.medtrol.com



Ph: 800-847-7180
Fx: 800-355-3027
E-mail: sales@medtrol.com

ACCEPTED
With COMMENTS
In EPA Letter Dated:
SEP - 9 2003

Under Federal Insecticide,
Fungicide and Rodenticide Act as
defined in the pesticide,
and under EPA Reg. No.]

69687-2

(Administrative Note: Bracketed text [] is optional versions of text for different packaging.)

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