6243-1

2/21/2002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 2 7 2002

Terry Sabatelli Regulatory Specialist Auto-Chlor System c/o DiverseyLever 3630 E. Kemper Rd. Cincinnati, OH 45241

Subject:

Auto-Chlor Solution-QA EPA Registration Number: 6243-1 Application Date: October 15, 2001 Receipt Date: December 7, 2001

Dear Terry Sabatelli:

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:

update label language

Conditions

Revise the label as follows:

1. Revise the Precautionary Statements by changing the word "or" to "and" in the statement: "Causes irreversible eye damage <u>and</u> skin irritation." Also delete the following phrase which is inappropriate for this product: "and rubber gloves when handling."

2. Revise the statement on the first page as follows: "For Institutional and Industrial Use Only"

3. Delete the following statement at the beginning of the left column on page two as this statement appears twice on the label: "Use Auto-Chlor Solution-QA in hospitals, nursing homes,

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restaurants, bars, institutional kitchens, hotels and motels, schools, penal and military institutions. This product is an effective sanitizer and disinfectant."

4. Revise the statement beginning: "this product is not to be used as a terminal sterilant/high-level..." to include: "...is introduced *directly* into the human body..."

5. Revise the directions for sanitizing food contact surfaces as follows: delete the phrase "...and other pre-cleaned hard nonporous surfaces with a cloth, mop, sponge and coarse sprayer..." by rewording as follows; "Apply use-solution to dinnerware and food utensils by immersion. For items which are too large for treatment by immersion, solution may be applied with a cloth, mop, sponge or coarse sprayer."

6. Revise the directions for disinfection/cleaning/deodorizing to begin as follows: "To disinfect inanimate, hard nonporous surfaces that include: floors, walls, tables, chairs, counter tops, garbage pails and other inanimate, hard nonporous surfaces *first remove heavy soil*. *Preclean*, then apply this product with..."

7. Revise the directions for Hospital Disinfection as follows: "...by adding 2 $\frac{1}{2}$ ounces of this product per 1 gallon of water."

8. Revise the following statement to read: "For use of this product as a cleaner and deodorizer, use 3-10 ounces per gallon of water. Apply product and remove excess or allow to air dry."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter please contact Tracy Lantz at (703) 308-6415.

Sincerely,

John Male

Velma Noble Product Manager (31) Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure: Stamped Label 7510C:T.Lantz:2/22/02:6243-1a

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

Corrosive: Causes irreversible eye damage or skin irritation. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eye wear (goggles, face shield, or safety glasses) and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, occans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDFS) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not store on side. Avoid creasing of side walls. Keep this product in locked storage sufficient to make it inaccessible to children and persons untamiliar with its proper use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of all excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Plastic containers – Triple rinse (or equivalent). Then 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.

ACCEPTED with COMMENTS in EPA Letter Dated: FEB 2 7 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesuicide, registered under EPA Reg. No. 6243-1

Auto-Chlor & SYSTEM Auto-Chlor Solution-QA

Sanitizer – Disinfectant - Deodorizer For Institutional, and Industrial Use

ACTIVE INGREDIENT:

n-alkyl (59% C14, 40% C12, 10% C16)	
dimethyl benzyl ammonium chloride	4.75%
OTHER INGREDIENTS	95.25° a
Total	100.000,

KEEP OUT OF REACH OF CHILDREN **DANGER**

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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 poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed

She left side panel for additional precautionary statements.

EPA Registration No.: 6243-1 EPA Establishment No. 875-OH-1

Manufactured for:

Auto-CLDr * System – Memphis, TN 24 Hour Emergency Telephone: Medical: (Call Collect) 303-592-1024 Transportation: (CHEMTREC) 800-424-9300

NET CONTENTS: 4 x 1 gallons, 5 gallons -

Use Auto-Chlor Solution-QA in hospitals, nursing homes, restaurants, bars, institutional kitchens, hotels and motels, schools, penal and military institutions. This product is an effective sanitizer and disinfectant.

DIRECTIONS FOR USE

It is a violation of Federal I aw to use this product in a manner inconsistent with its labeling.

This product is not to be used as a terminal sterilant high-level disinfectant on any surface or instrument that (1) is introduced 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 barrier or otherwise enter normally sterile areas of the body.

Use Auto-Chlor Solution-QA in hospitals, nursing homes, restaurants, bars, institutional kitchens, hotels and motels, schools, penal and military institutions. This product is an effective sanitizer and disinfectant. This product can be used of hard, nonporous surfaces such as: walls, floors, countertops, stainless steel surfaces, dishes, cooking utensils, silverware, glassware, appliances, and sinks.

SANITIZING FOOD CONTACT SURFACES:

Use 1/2 ounce per 1 gallon of water 200 ppm active of Auto-Chlor Solution-QA for sanitizing and cleaning of equipment and utensils in hospitals, nursing homes, restaurants, bars, and institutional kitchens. Prior to application remove gross food particles and soil by a preflush, or pre-scrape and, when necessary, pre-soak treatment. Follow with thorough washing in a good detergent or compatible cleaner, followed by a potable water rinse before applying sanitizer. Apply use-solution to dinnerware, and food utensils and other precleaned hard nonporous surfaces with a cloth, mop, sponge, and coarse sprayer or by immersion. Treated surfaces must remain wet for 60 seconds (1 minute). Drain thoroughly and allow to air dry before reuse. No potable water rinse is required after application of sanitizer. Fresh solutions must be prepared at least daily or sooner if solution becomes diluted or soiled.

At ½ oz. per gallon of water this product fulfills the criteria of Appendix of Grade "A" Pasteurized Milk Ordinance, 1995 Recommendations of the U.S. Public Health Service in water up to 550 ppm (32 grains per gallon) hardness calculated as CaCO₃ when tested by the AOAC Germicidal and Detergent/Sanitizing Official Method.

DISINFECTION / CLEANING / DEODORIZING DIRECTIONS:

To disinfect pre-cleaned, inanimate, hard nonporous surfaces that include: floors, walls, tables, chairs, counter tops, garbage pails and other inanimate hard nonporous surfaces, apply this product with mop, cloth, sponge or hand-pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. For heavily soiled areas a pre-cleaning step is required. Prepare a fresh solution daily or more often if the use solution becomes visibly soiled or diluted

General Disinfection: Use this product to disinfect pre-cleaned, inanimate hard nonporous surfaces in educational, penal, military institutions, institutional and hotel and motels. Prepare a use solution by adding (mixing) 1 1/3 ounces of this product per 1 gallon of water. At this use level, this product is effective against staphylococcus aureus and salmonella choleraesuis.

Hospital Disinfection: Use this product in hospitals and nursing homes and other health care institutions by adding 2 $\frac{1}{2}$ ounces per gallon of this product per 1 gallon of water. At this use level this product is effective against pseudomonas aerginosa.

For heavily soiled areas, a pre-cleaning step is required.

For use of this product as a cleaner and deodorizer, use 3 - 10 ounces per gallon of water is recommended.

ACCEPTED with COMMENTS in EPA Letter Dated:

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