

10088-42

04-13-2004

1/2

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 13 2004

Mr. Troy Munson  
Regulatory Compliance Specialist  
Athea Laboratories, Inc.  
P.O. Box 240014  
Milwaukee, WI 53224

Subject: 10% Disinfectant Sanitizer  
EPA Registration No. 10088-42  
Application Date: 1/12/04  
Receipt Date: 1/14/04

Dear Mr. Munson:

The following amendment, submitted in connection with registration under the Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable:

Response to PR Notice 2001-1

**LABEL COMMENTS**

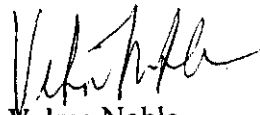
Expand the "Cold Disinfection" directions by adding the following language: Rinse thoroughly and dry before use. Fresh solution should be prepared daily or more often if solution becomes cloudy or soiled.

**GENERAL COMMENTS**

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble

Product Manager 31

Regulatory Management Branch 1

Antimicrobial Division (7510C)

CONCURRENCES							
SYMBOL	1510C						
SURNAME	Z. Jones						
DATE	4-9-04						

**PRECAUTIONARY STATEMENTS**  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER**

Causes severe eye and skin damage. Do not get in eyes or on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Avoid contamination of food.

**FIRST AID**

<b>If in eyes:</b>	<ul style="list-style-type: none"> <li>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.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin or clothing:</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed:</b>	<ul style="list-style-type: none"> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>

**HOT LINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the **National Pesticide Information Center 1-800-858-7378** for emergency medical treatment information.

**NOTE TO PHYSICIAN**

Probable mucosal damaged may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

**ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirement of a National Pollutant Discharge Elimination System (NPDES) 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 or disposal. Store in a dry place no lower in temperature than 50°F. or higher than 120°F.

**CONTAINER DISPOSAL:** 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 local authorities, by burning. If burned, stay out of smoke.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

# 10% DISINFECTANT SANITIZER

**ACTIVE INGREDIENTS:**

n-Alkyl (60% C<sub>14</sub>, 30% C<sub>16</sub>, 5% C<sub>12</sub>, 5% C<sub>18</sub>)dimethyl benzyl ammonium chloride ..... 5.00%  
n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>)dimethyl ethylbenzyl ammonium chloride ..... 5.00%

**INERT INGREDIENTS:** ..... 90.00%  
**TOTAL** ..... 100.00%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

See side panel for additional precautions and first aid instructions.

EPA REG. NO. 10088-42  
EPA EST. NO. 10088-WI-1

Manufactured By:

**Athea Laboratories Inc.**  
**P. O. Box 240014**  
**Milwaukee, WI 53224**

**ACCEPTED**

APR 13 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 10088-42

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its label.

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 barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

**HOUSEHOLD:** For sanitizing and disinfecting floors, walls, and inanimate hard surfaces, including locker rooms, garbage pails, sink tops, corridors, classrooms, offices and shower stalls. Kills Staphylococcus aureus and Salmonella choleraesuis. For heavily soiled or contaminated areas, a pre-cleaning step is recommended. To disinfect, use 3 ounces per 5 gallons of water. To sanitize, use 1 ounce per 4 gallons of water. Apply solution to surfaces with a mop or a cloth.

**HOSPITALS:** For floors, walls and other hard surfaces in hospitals, nursing homes, and institutions, including sink tops, garbage pails, telephones, and restrooms. Use 3-1/2 ounces per 5 gallons of water, and apply with a cloth, mop, or sponge. For heavily soiled or contaminated areas, a pre-cleaning step is recommended. When used on environmental inanimate hard surfaces at 3-1/2 ounces per 5 gallons of water, this product is effective against: Influenza A2, Herpes Simplex, Adenovirus type 2, Vaccinia viruses, and Pseudomonas aeruginosa PRD-10.

**COLD DISINFECTION:** For disinfection of previously cleaned surgical instruments, barber tools, and dental equipment, submerge instruments into solution containing 1-1/2 ounces per gallon of water for 10 minutes.

**RESTAURANT & BAR RINSE:** For dishes, glassware, silverware, utensils, wash with soap or detergent to remove gross food particles and soil, rinse thoroughly with potable water and immerse in a sanitizing solution containing 1 ounce per 4 gallons of water (200 ppm of active quaternary). A contact time of at least 1 minute is required for sanitization, then drain sanitizing solution thoroughly and air dry. No potable water rinse is required. Prepare fresh sanitizing solution daily or more often if solution becomes diluted or soiled.

**FOOD PROCESSING EQUIPMENT:** For sanitization of previously cleaned food processing equipment, hard surfaces, and utensils. Scrape, flush or pre-soak to remove gross food particles and soil and wash thoroughly with detergent or compatible cleaner followed with a potable water rinse. Spray, flood or immerse to wet all surfaces completely with a solution containing 1 ounce per 4 gallons of water (200 ppm of active quaternary). A contact time of at least 1 minute is required for sanitization, then drain the sanitizing solution thoroughly and air dry. No potable water rinse is required. Prepare fresh sanitizing solution daily or more often if the solution becomes diluted or soiled.

**DAIRY:** To sanitize dairy equipment such as tanks, lines, pails and milk cans, first wash thoroughly with detergent or compatible cleaner to remove soil, and rinse thoroughly with a potable water rinse. Spray, flood or fill piping to wet all surfaces thoroughly with a solution containing 1 ounce per 4 gallons of water (200 ppm of active quaternary). A contact time of at least 1 minute is required for sanitization, then drain the sanitizing solution thoroughly and air dry. No potable water rinse is required. Prepare fresh sanitizing solution daily or more often if the solution becomes diluted or soiled. Consult local health board for additional information.

0172.010904

**NET CONTENTS:**

☐ 1 ☐ 5 ☐ 6 ☐ 20 ☐ 30  
☐ 35 ☐ 55 Gallons

2/2