

10088-52

11/17/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 17 2004

Mr. Troy Munson
Athea Laboratories
P.O. Box 240014
Milwaukee, WI 53324

Subject: Lemon Scented Disinfectant Cleaner
EPA Registration No. 10088-52
Amendment Date: July 2, 2004
EPA Receipt Date: July 6, 2004

Dear Mr. Munson,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Revise the "Precautionary Statements" to reflect the updated language in the Label Manual 3rd Edition, chapter 8 by stating:

Corrosive. Causes irreversible damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or faceshield, protective clothing, and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

2. Under the "To Disinfect" directions, delete operating rooms and specify operating room tables and floors. Also, revise the directions to read:

For heavily soiled areas, a preliminary cleaning is recommended. Apply 2 oz. per gallon of water to hard nonporous surface with a mop, cloth, or sponge, thoroughly wetting surfaces. Treated surfaces must remain wet for 10 minutes. Wipe dry with cloth, sponge or mop, or allow to air dry. Prepare a fresh solution daily or more often if the use solution becomes visibly soiled or diluted.

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3. Since this product may be used as a cleaner, deodorizer, and fungicide, you must add the following specific use directions.

- A) **To Clean and Deodorize:** Mix 2 oz per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge, or sprayer. Wipe or allow to air dry.
- B) **Fungicidal Directions:** At 2 oz. per gallon of water this product is effective against the pathogenic fungi, *Trichophyton mentagrophytes* (the Athlete's Foot Fungus) for use in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities. Follow disinfection directions.

4. The Agency has asked registrants to begin submitting "Master" labels which contain all the claims, use sites, directions, storage/disposal statements, and environmental hazard statements on one label. Based on the "Application for Pesticide," this product is sold in containers ranging from 1 gallon containers to 55 gallon drums. You should revise your label to bring it into compliance with the above criteria for a "master label by addressing the following comments:

A) Revise the Storage and Disposal section as follows:

(For containers greater than 1 gallon)

Storage and Disposal

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

Pesticide Storage: Keep container closed when not in use in an area inaccessible to children and persons unfamiliar with its use. Store in a dry place no lower in temperature than 50° or higher than 120°F.

Pesticide Disposal: Statements are acceptable.

Container Disposal: Statements are correct.

(For containers 1 gallon or less)

Storage and Disposal

Keep container closed when not in use in an area inaccessible to children and persons unfamiliar with its use. Store in a dry place no lower in temperature than 50° or higher than 120°F. Do not reuse empty container. Discard in the trash.

B) You should note that only containers greater than 5 gallons are required to carry the Environmental Hazard statements.

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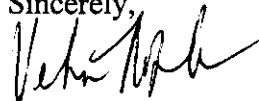
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General Comments

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

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

Enclosure: Stamped Label

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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

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.
If on skin or clothing:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none"> Call a 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.

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.

LEMON SCENTED DISINFECTANT CLEANER

CLEANER, DEODORIZER, DISINFECTANT, FUNGICIDE

ACTIVE INGREDIENTS:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)dimethyl benzyl ammonium chloride	2.25%
n-Alkyl (68% C ₁₂ , 32% C ₁₄)dimethyl ethylenbenzyl ammonium chloride	2.25%
INERT INGREDIENTS:	95.50%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

See side panel for additional precautions and first aid instructions.

EPA REG. NO. 10088-52
EPA EST. NO. 10088-WI-1

Manufactured By:

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 17 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 10088-52

DESIGNED FOR HOSPITAL AND INSTITUTIONAL USE

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.

This cleaner and disinfectant is designed for use in institutions such as HOSPITALS, NURSING HOMES, and SCHOOLS where housekeeping will be of prime importance in controlling the hazard of cross-infection. It is effective against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Pseudomonas aeruginosa* PRD-10 (substantiated by the AOAC Use Dilution Confirmation Test). It is also effective against pathogenic fungi *Trichophyton interdigitale*.

When used on environmental hard surfaces at 2 ounces per gallon of water, this product is also effective against:

- Influenza A2 (Flu virus)
- Herpes Simplex (Cold sores, fever blisters)
- Adenovirus type 2, (Acute respiratory disease)
- Vaccinia (Smallpox virus)

TO DISINFECT: For floors, walls, sink tops, garbage pails, telephones, restrooms, bed pans and operating rooms and other hard, inanimate surfaces, use 2 ounces per gallon of water. Apply with a cloth or mop to walls, floors and other hard surfaces.

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: Do not re-use the empty container. 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: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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NET CONTENTS:

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 35 55 Gallons

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