

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 9 2003

Mr. Robert J. Sloan
Sr. Regulatory Services Associate
H & S Chemicals Division c/o Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: **Formulation AE-3328**
EPA Registration Number 47371-48
Application Dated July 10, 2003
EPA Receive July 14, 2003

Dear Mr. Sloan:

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

Proposed Amendment:

- revise first aid statement
- revise precautionary statements and storage and disposal

General Comment:

1. Revise Precautionary statement as follows"

May be fatal if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water .

2. Under the "Storage and Disposal" add the statement "Do not contaminate water, food or feed by storage".

3. Your label includes the sites "other institutions" and "sick rooms". The listing of these two sites implies that this product is for use in hospital settings. According to DIS/TSS-1 the following organisms are required to support hospital use of a disinfectant: Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa. Your label does not list any of these organisms, thus these sites ("other institutions" and "sick rooms") must be deleted from the label.

SYMBOL								
SURNAME								
DATE								

- 4. Add "For Disinfection" to "General Use Instructions".

Other Comments:

- 1. Based on the signal word Danger as per 40 CFR Part 157.21 and 157.22, Child Resistant Packaging is required for this product. Submit certification to the Agency as per 157.34 that this type of packaging is being used.

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy 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 Drusilla Copeland on (703) 308-6224.

Sincerely,



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

Enclosure

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

IF SWALLOWED: 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

PHYSICAL AND CHEMICAL HAZARDS

Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting. Never throw container into fire or incinerator. Avoid getting concentrate in eyes.

STORAGE AND DISPOSAL

Store in areas inaccessible to children. Do not reuse empty container.

CONTAINER DISPOSAL

This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label (DO NOT PUNCTURE!). If recycling is not available, replace cap and discard container in trash

FORMULATION AE-3328

Disinfectant bathroom cleaner

Active Ingredients:

n-Alkyl (C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%)	
dimethyl benzyl ammonium chloride	0.10%
n-Alkyl (C ₁₂ 68%, C ₁₄ 32%)	
dimethyl ethylbenzyl ammonium chloride...	0.10%
Other Ingredients:	<u>99.80%</u>
Total:.....	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

(See side panel for additional precautionary statements.)

EPA Reg. No. 47371-48

EPA Est. No. (insert EPA Establishment No. here)

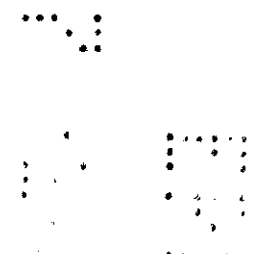
Net Contents (insert container size here)

H&S CHEMICALS DIVISION
c/o Lonza Inc.
17-17 Route 208
Fair Lawn, New Jersey 07410

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 47371-48



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Effective against odor-causing bacteria. For use in the household, schools & colleges, hotels, motels, office buildings & other institutions.

Removes dirt, mildew and mold stains, bathtub ring, soap film. Leaves a shiny surface. Easy cleaning, spray on and wipe off. Deodorizes as it cleans.

For use on bathtubs, sinks, walls, shower stalls, cabinets, garbage cans, kitchen counters. For use in the laundry room, diaper pails, sick rooms, and pet areas.

DIRECTIONS FOR USE

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

GENERAL USE INSTRUCTIONS

Shake well before using. Hold can 6 to 8 inches from surface to be cleaned. Spray area completely with foam. Apply to walls, floors, garbage cans, and other hard (inanimate) nonporous surfaces such as tables, chairs, countertops, sinks, and bathroom fixtures with a cloth so as to thoroughly wet surfaces for a contact time of 10 minutes. For heavily soiled areas, a preliminary cleaning is required. Wipe dry with a clean cloth or sponge or allow to air dry.

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Fungicide, and Rodenticide Act as
amended, for the pesticide,
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