

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

Subject: Formulation AE-90
EPA Registration No. 47371-89
Amendment Date: August 20, 2003
EPA Receipt Date: August 22, 2003

NOV 20 2003

Dear Mr. Sloan,

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.

- Addition of Directions for Use

Conditions

1. As stated in our June 7, 2001 letter, we were unable to find data to establish an Acute Toxicity profile for this product. Since that time we have reviewed a number of product labels containing the same or similar ingredients. We note that there is a comparable Lonza product 47371-177. Although these products are different from each other we now feel that we can provide a toxicity profile for this product. We certainly encourage you to conduct toxicity studies on this product if you feel this profile in incorrect.

Revise your label to include the following Precautionary and First Aid statements based on this profile:

Acute Oral	IV
Acute Dermal	III
Acute Inhalation	III
Skin Irritation	III
Eye Irritation	III

CONCURRENCES

SYMBOL	J5100						
SURNAME	J. J. J.						
DATE	11/20/03						

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Precautionary Statements:

"Harmful if absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing vapor or spray. Wash thoroughly with soap and water after handling."

First Aid Statements:

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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

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."

3. Revise the "Storage and Disposal" section as follows:

A. After the heading STORAGE AND DISPOSAL, add the following statement:

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

B. Add the subheading PESTICIDE STORAGE before the sentence "Store in areas inaccessible to children."

C. Revise the last three sentences of the "Container Disposal" section as follows:

Before offering for recycling, empty the can by using the product according to the label. If recycling is not available, replace cap and discard container in trash. Do not incinerate or puncture.

4. On page 2 of the label, remove the word "(Prevents)" from the phrase: "Controls (Prevents) mold and mildew." Data to support a residual claim (prevents) has not been submitted to support this statement.

5. In the "Disinfection Directions for Kennels . . ." on page 3 of the label, reinsert the word in italics in the following sentence. The product is not to be used to disinfect food contact surfaces. The last accepted label for this product correctly indicated this.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

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HIGHLIGHTED COPY

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

PHYSICAL AND CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:
NOV 20 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-89

FORMULATION AE-90

One-step Disinfectant, Cleaner, and Deodorant

BACTERICIDAL FUNGICIDAL
MILDEWSTATIC *VIRUCIDAL

A ready-to-use, multi-purpose formula effective in the presence of a moderate amount of soil (5% organic serum) against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Trichophyton mentagrophytes*, *Herpes simplex type 2, and *HIV-1 (AIDS virus).

Active Ingredients:

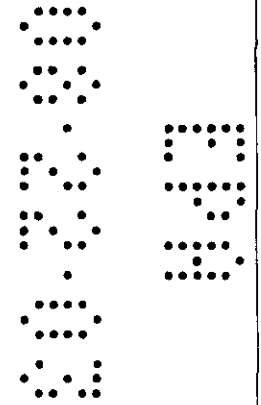
n-Alkyl (C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%)	
dimethyl benzyl ammonium chloride	0.09%
n-Alkyl (C ₁₂ 50%, C ₁₄ 30%, C ₁₆ 17%, C ₁₈ 3%)	
dimethyl ethylbenzyl ammonium chloride	0.09%
Other Ingredients:	99.82%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 47371-89
EPA Est. No. (as indicated on container)
Net Contents: (as indicated on container)

H&S Chemicals Division,
c/o Lonza Inc.
17-17 Route 208, Fair Lawn, NJ 07410



- Broad-spectrum activity.
- Hospital-use disinfectant effective against *Staphylococcus aureus* (Staph), and *Pseudomonas aeruginosa* (*Pseudomonas*).
- Non-acid and non-abrasive; will not etch or scratch delicate surfaces.
- Effective against *HIV-1 (AIDS virus) and *Herpes simplex type 2.
- Controls (Prevents) mold and mildew.
- Dissolves soap scum and foams away dirt.
- Disinfects, cleans, and deodorizes in one labor-saving step.
- Contains no CFCs or other ozone depleting substances
- Federal regulations prohibit CFC propellants in aerosols
- Deodorizes those areas which generally are hard to keep fresh smelling (such as garbage storage areas, empty garbage bins and cans, basements, restrooms, and other areas prone to odors caused by micro-organisms).
- When used as directed, demonstrates effective disinfection against *Staphylococcus aureus*, *Salmonella Choleraesuis* and *Pseudomonas aeruginosa*, thus meeting AOAC Use Dilution Test requirements for hospital disinfectant. Efficacy tests have demonstrated that it is an effective one-step cleaner disinfectant in the presence of organic soil (5% blood serum)
- This product is fungicidal against pathogenic fungi (T. mentagrophytes) when used as directed on hard surfaces found in the bathroom, shower stall and locker room, or other clean, hard, nonporous surfaces commonly contacted by bare feet.

DIRECTIONS FOR USE

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

SHAKE BEFORE USING

GENERAL USE DIRECTIONS: Recommended for use in households, basements, restrooms, hospitals, nursing homes, institutions, offices, schools, colleges, airports, hotels, motels, greenhouses, and kennels. Disinfects, cleans, and deodorizes non-porous, inanimate surfaces such as floors, walls, metal surfaces, stainless steel surfaces, plastic surfaces (such as polypropylene, polystyrene, etc.), plastic/vinyl chairs, glazed porcelain, garbage cans, laundry chutes (opening and the surfaces within 12-24 inches of the opening), bathroom fixtures, sink tops, shower stalls, exterior bowl surfaces, empty basins, knobs, handles, railings, tables, chairs, telephones, bathrooms, bathtubs, hampers, cabinets, bed springs, vehicles (ships, trains, and airplanes), and many other similar public and residential surfaces which could harbor and transmit dangerous microorganisms.

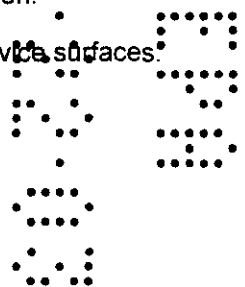
TO CLEAN: Shake can. Spray evenly over surface, allowing sufficient time for the foam to penetrate heavy soil deposits. Wipe off. Chrome fixtures may be rinsed for high shine.

TO DISINFECT: Clean surface thoroughly as instructed above. Then apply a thin coat of foam, making sure to cover entire surface to be disinfected. Allow foam to remain for at least 10 minutes, then wipe off or allow to air dry.

(For labels that list medical premises and / or metal and / or stainless steel surfaces, one of the following statements must be used:)

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 medical devices prior to sterilization or high level disinfection.

or
This product is not for use on medical device surfaces.



MILDEWSTATIC INSTRUCTIONS: Follow the disinfection instructions above. Repeat application weekly or when growth reappears.

FUNGICIDAL DIRECTIONS: Kills Trichophyton mentagrophytes (the cause of athlete's foot fungus) on environmental surfaces. For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities on surfaces such as floors and shower stalls. Follow disinfection directions.

***KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal Protection: Disposable protective gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and during decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 5 minutes at (25°C.) (77°F) (room temperature). Use a 10-minute contact time for disinfection against all other viruses, fungi, and bacteria listed.

Disposal of Infectious Materials: Blood / body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

DIRECTIONS FOR FOOD PROCESSING ESTABLISHMENTS:

For use on non-food, contact surfaces such as floors, walls, tables, empty garbage bins and cans. When used in food processing establishments, cover or remove all food and packaging materials, remove all gross soils, saturate all surfaces with the spray product, scrub to loosen all soils, allow to soak for 10 minutes, thoroughly rinse all wetted and cleaned surfaces with potable water.

TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS:

Empty toilet bowl or urinal. Remove gross filth before disinfection. Thoroughly clean exposed surfaces with soap or detergent. Shake can. Apply a thin coat of foam, making sure to cover entire surface to be disinfected. Brush or swab thoroughly, including under the rim, allow foam to remain for at least 10 minutes, then flush.

DISINFECTION DIRECTIONS FOR KENNELS AND OTHER AREAS THAT HOUSE ANIMALS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls, and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a thin coat of foam for a period of 10 minutes. Saturate all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure with a thin coat of foam for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

