

47371-89

8/7/2003

Page 185

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 7 2003

Robert Sloan
Senior Regulatory Services Associate
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 dated: May 12, 2003
EPA Received date: May 13, 2003

Dear: Mr. Robert Sloan,

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

Proposed Amendment

- Add use directions for Food Processing Establishments
- Add use directions for toilet bowls and urinals.
- Add optional Marketing language
- Other minor changes as shown on the highlighted copy of the proposed label

Conditions

Revise the label as follows:

1. Toilet Bowl and Urinal Disinfectant/Cleaner directions must include the following statements:

a) Remove gross filth prior to disinfection

b) Brush or swab thoroughly and allow foam to remain for at least 10 minutes, then flush

2. Disinfection Directions for Kennels and Other Areas that House Animals must include the following statement:

Immerse 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.

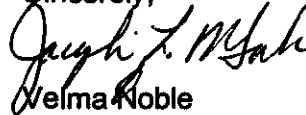
		CONCURRENCES					
SYMBOL	7510(c)						
JURNAME	ATB-105						
DATE	8/5/03						

General Comments

A stamped label is enclosed for your records. Please submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. If the above comments are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch 1

Antimicrobial Divisions (7510c)

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

Keep product under locked storage, 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:
AUG 7 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 and free of odors. Areas include basements, restrooms, 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, refrigerators, bathtubs, hampers, cabinets, washbasins, vehicles (ships, trains, and airplanes), and many other similar public and residential surfaces which could harbor and transmit dangerous microorganisms.

• When used as directed, demonstrates effective disinfection against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*, thus meeting AOAC USA Dilution Test requirements for hospital disinfectant. Efficacy tests have demonstrated that it is an effective broad-spectrum disinfectant in the presence of organic soil.

• This product is not a fungicide, although it will kill mold and mildew when used as directed on hard surfaces such as floors, walls, shower stalls and locker rooms, or other clean, hard, non-porous 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, refrigerators, bathtubs, hampers, cabinets, washbasins, vehicles (ships, trains, and airplanes), and many other similar public and residential surfaces which could harbor and transmit dangerous microorganisms.

(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.

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.

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 (room temperature) (77°F). 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 soil, 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 / GERMICIDE
Thoroughly clean
Shake
to cover
Allow foam to
remain for at least 10 minutes after flush.

DISINFECTION DIRECTIONS FOR KENNELS AND OTHER AREAS THAT HOUSE ANIMALS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not 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. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

