

47371-89

6/7/2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

JUN 07 2001

ATTENTION: Michael Counts

SUBJECT: Formulation AE-90  
EPA Registration Number 47371-89  
Your Amendment Dated: March 7, 2001  
EPA Received Date: March 9, 2001

The amendment referred to above, submitted in connection with registration under FIFRA as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. We are unable to find data to support the Acute Toxicity data requirements for this product. Please be advised that at product reregistration Acute Toxicity data are likely to be required to support the reregistration of this product. At this time, add the signal word "Caution" directly below the text "Hazards to Humans and Domestic Animals".

B. Revise the "Storage and Disposal" instructions exactly as follows:  
1. Place the statement "Do not contaminate water, food, or feed by storage or disposal." directly below the heading "Storage and Disposal".  
2. Place the heading "Pesticide Storage" immediately before the statements beginning "Keep product under locked..." and ending "...empty container."  
3. Include the following statements in this section:

**"Pesticide Disposal**  
*Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."*

C. Revise the Ingredients Statement to include the phrase "Total.....100%"

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SYMBOL	7500C						
SURNAME	S. Lopez						
DATE	6/7/01						

D. The front panel of your label lists the following organisms which are supported by efficacy data: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Trichophyton mentagrophytes*, *Herpes simplex type 2* and *HIV-1 (AIDS virus)*. The second panel of the label states "Hospital-use disinfectant effective against Staph, Strep, and *Pseudomonas*." According to our records no efficacy data has been submitted to support the effectiveness of this product against an organism in the genus *Streptococcus*. In addition, abbreviated names of these microorganisms may only be used when associated with the complete name of the organism. Thus you are required to revise the statement: "Hospital-use disinfectant effective against Staph, Strep, and *Pseudomonas*." to read exactly as follows: "*Hospital-use disinfectant effective against Staphylococcus aureus (Staph) and Pseudomonas aeruginosa (Pseudomonas)*."

E. Clarify the site "laundry chutes". Revise your label to state exactly as follows: "laundry chutes (*opening and the surfaces within 12-24 inches of the opening*)". This revision is required since it is reasonable that this product may only be applied in the first 1 to 2 feet of a chute or a length equal to the distance within the chute which may be reached by the applicator (i.e. arm's length).

F. Delete the use of this product to disinfect garbage disposal units. The present directions do not ensure adequate coverage of the foam on all surfaces within the disposal. Provide us with detailed information that demonstrates that the user is able to apply enough product such that all surfaces within the disposer can be adequately contacted. In addition, your proposed label must provide more complete directions as to how a product applied as a foam should be used (i.e. how long to spray and/or how much to spray into the disposal unit.)

G. Add the following text as directions for use as a fungicide against *Trichophyton mentagrophytes*.

*"Kills Trichophyton mentagrophytes-the fungus causing athlete's foot, 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."*

H. Add the following text as directions for use in kennels, schools and colleges in areas where animals are housed.

***"Instructions for use in Kennels and other areas which 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 premise, 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."*

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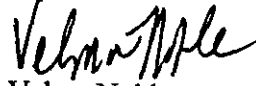
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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2. Submit two ( 2 ) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure (Stamped Label)  
7510C:T.Lantz:6/4/01:47371-89

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

**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:  
**JUN 07 2001**

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 (C14 60%, C16 30%, C12 5%, C18 5%)  
dimethyl benzyl ammonium chloride .....0.09%  
n-Alkyl (C12 50%, C14 30%, C16 17%, C18 3%)  
dimethyl ethylbenzyl ammonium chloride .....0.09%  
INERT INGREDIENTS:.....99.82%

**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 Staph. Strep, and 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 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

**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, hospitals, nursing homes, 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, bathroom fixtures, shower stalls, exterior bowl surfaces, empty basins, knobs, handles, railings, 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 surfaces, allowing sufficient time for the foam to penetrate.

FORMULATION AE-90  
EPA Reg. No. 47371-89  
EPA LABEL approved XXX

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.

**FOR GARBAGE DISPOSAL UNITS:**

**STEP 1: Clean & Deodorize -** Shake can. Make sure disposal unit is empty and turned off. For best results, run hot water into sink for 1 minute to soften soils. Turn off water, let drain and shake can and spray foam into disposal opening until disposal is filled with foam. Allow foam to remain for 10 minutes. Turn on disposal and rinse with more hot water.

**STEP 2: Disinfect -** Spray foam into disposal. Allow to remain for at least 10 minutes then let air dry.

USE WEEKLY OR AS OFTEN AS NEEDED.

\*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 latex or vinyl 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). 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.

ACCEPTED  
COMMENTS  
JUN 07 2001

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