

41121 6836-86 1075
 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Lonza, Inc.
 17-17 Route 208
 Fair Lawn, NJ 07410

Attn: Eliot Harrison; Delta Analytical Corporation,
 Authorized Agent for Lonza, Inc.

Subject: Lonza Formulation DC-101
 EPA Registration No. 6836-86
 Your Submissions of June 30, 1994 and August 15, 1995

The respective submissions noted above, a proposal to add alternate product formulations under the subject registration, and revised product labeling, have completed review. Please note the following.

1. With regard to the June 30, 1994 amendment which proposed five alternate product formulations and included 6 corresponding revised Confidential Statements of Formula (CSFs, 1 basic, 5 alternate), the following comments apply:

a. The CSF pertaining to the basic product formulation and the CSF designated as alternate formula #1 agree with the product label, are in compliance with PR Notice 91-2 and are acceptable.

b. The remaining June 30, 1994 CSFs, designated as alternate formulations "2", "3", "4" and "5", cannot be accepted without provision of the chemical identity and composition of the listed dye component "Keyacid Green G Extra".

2. The proposed revised product labeling submitted August 15, 1995 in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comment listed below. A stamped copy is enclosed for your records. Submit one copy of the finished labeling before releasing the product for shipment.

a. In light of the August 30, 1995 6(a)(2) submission received by EPA under this registration which indicated product failure against the bacterial pathogen Escherichia coli, this organism must be removed from the product label. (Page 2 of the submitted draft label.) A response to the 6(a)(2) submission is reserved until further review.

CONCURRENCES

SYMBOL	75053						
SURNAME	<i>Luatogian</i>						
DATE							

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,

Robert Travaglini

Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry.

LONZA DC-101 has been formulated to aid in the reduction of cross contamination in these areas.

LONZA DC-101 is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA DC-101 is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, **LONZA DC-101** will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

LONZA DC-101 will remove hard water deposits and limestone buildups when used as directed.

LONZA DC-101 is recommended for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, transportation terminals, hotels and motels.

For use in households.

Janitorial

LONZA DC-101 is a mild acid pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

LONZA DC-101 is a concentrate that can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

LONZA DC-101 provides effective cleaning strength in removing difficult to clean soap scum, and hard water deposits.

LONZA DC-101 maximizes labor results by effectively controlling odors.

Household

LONZA DC-101 Cleans, shines, deodorizes and disinfects all non-porous household surfaces. Inhibits the growth of mold and mildew, leaving bathrooms & kitchens clean and smelling fresh.

LONZA DC-101 is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

LONZA DC-101 is for use in kitchens, bathrooms and other household areas.

LONZA DC-101 may be applied to bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, walls, floors and other hard (inanimate) non-porous surfaces (such as metal, stainless steel, glazed porcelain, ceramic, and plastic).

LONZA DC-101 kills household germs in minutes; effective against harmful pseudomonas, staph and strep, while effectively controlling mold and mildew.

LONZA DC-101 is formulated to dissolve soap scum, corrosion and hard water deposits without scouring. Spray on - it clings and works on shower walls, glass doors, chrome, stainless steel and fiberglass, while you enjoy the fresh clean deodorizing fragrance.

LONZA DC-101 has been used to clean hard, non-porous inanimate surfaces for over 10 years. Proven effective on all of the toughest bathroom problems.

LONZA DC-101 penetrates and dissolves soap scum, ground-in dirt and grime, mineral deposits, and hard water stains, and kills household germs. Cleans and shines without abrasive scouring action. Deodorizes, too! Leaving your bathroom smelling minty fresh. **WHERE TO USE:** All bathroom tile, fiberglass, shower walls and doors, tubs and sinks, chrome fixtures, and toilet bowls.

Note: Some older tubs or sinks may be etched or discolored by **LONZA DC-101**. Test on small hidden area first. Do not use on decorative brass fixtures, polished aluminum, natural or synthetic marble. Do not place container on formica.

LONZA DC-101 is a Hospital Disinfectant, bactericidal at 1:32 dilution (4 ounce per gallon) according to the AOAC Use-Dilution Test method, modified in the presence of 400 ppm hard water plus 5% organic serum against:

Pseudomonas aeruginosa Salmonella choleraesuis
Staphylococcus aureus

LONZA DC-101 is a Hospital Disinfectant, bactericidal at 1:43 dilution (3 ounce per gallon) according to the AOAC Use-Dilution Test method, modified in the presence of 250 ppm hard water plus 5% organic serum against:

Pseudomonas aeruginosa Klebsiella pneumoniae
Staphylococcus aureus Proteus mirabilis
Salmonella choleraesuis Salmonella typhi
Brevibacterium Serratia marcescens
ammoniagenes
Enterobacter aerogenes Shigella dysenteriae
Escherichia coli Streptococcus pyogenes

LONZA DC-101 is virucidal* at 1:43 dilution (3 ounce per gallon) according to the virucidal quality test modified in the presence of 400 ppm hard water plus 5% organic serum against:

HIV-1 (AIDS virus) Herpes Simplex Type 1
Herpes Simplex Type 2

LONZA DC-101 is a sanitizer for hard and non-porous non-food contact surfaces at 0.75 ounce per 1 gallon dilution against:

Klebsiella pneumoniae Staphylococcus aureus

AGREED
with COMMISSIONER
to EPA Letter Dated

DEC - 1 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the pesticide
regulation under EPA Reg. No.

6836-86

Directions for Use

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

General use directions

Apply **LONZA DC-101** to bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, walls, floors and other hard (inanimate) non-porous surfaces (such as metal, stainless steel, glazed porcelain, ceramic, and plastic), thoroughly wetting surfaces as required. **LONZA DC-101** can be applied with a cloth, mop, sponge, or soaked or sprayed. For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse spray device. Spray with quick full strokes 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray mist. After use; close nozzle.

Disinfection directions

Add 3 oz. per gallon of water (4 oz. per gallon of hard water), to disinfect hard, non-porous surfaces. Treated surfaces must remain wet for 10 minutes. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

Virucidal directions

Add 3 oz. per gallon of water, for disinfection against all viruses claimed. Treated surfaces must remain wet for 1 minute. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

Mold and Mildew Control directions

Add 3 oz. per gallon of water, to inhibit the growth of mold and mildew and their odors on hard, non-porous surfaces. Thoroughly wet all treated surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappear.

Sanitizing Non-Food Contact Surface directions

0.75 oz. per 1 gallon of water, to sanitize hard porous and nonporous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

Toilet Bowl Disinfectant/Cleaner directions

From concentrate: Add 3 oz. to the toilet bowl and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From use-solution: Empty toilet bowl or urinal and apply a 4 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, allow to stand for 10 minutes and flush.

Heavy Duty Cleaner/Disinfectant directions

To clean, deodorize and disinfect, and control the growth of mold and mildew (use from 1:10 dilution up to full strength) (use full strength). For cleaning and deodorizing shower stalls and shower fixtures: starting at the bottom and working toward the top, simply foam on the surface and spread with a brush, sponge or cloth. Let set for a minute, agitate to loosen stubborn accumulations and then rinse with water. For cleaning and deodorizing toilet bowls, squirt foam on exposed surfaces including under the rim. Agitate thoroughly with brush, swab, sponge or cloth. Allow to soak for a few minutes then flush. To disinfect, treated surfaces must remain wet for 10 minutes; for HIV-1 (AIDS Virus) and Herpes Simplex Types 1&2 treated surfaces must remain wet for 1 minute using the undiluted product. For heavy soiled areas, a preliminary cleaning is required.

*** KILLS HIV-1 ON PRE-CLEANED 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 or body fluids and in which the surfaces/objects likely to be soiled with blood or 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 ON SURFACES /OBJECTS SOILED WITH BLOOD/BODY FLUIDS."

PERSONAL PROTECTION: Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of **LONZA DC-101**.

CONTACT TIME: Leave surface wet for 1 minute with 3 oz. per gallon use-solution. Use a 10 minute contact time for disinfection against all other bacteria, claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PELIGRO:

Si no sabe el inglés, solicite instrucciones a su supervisor antes de usar este producto.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC - 1 1995

Fungicide, Disinfectant and Antimicrobial
amended, for the pesticide
registered under EPA Reg. No.

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

6836-86