

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO.

6836-227

DATE OF ISSUANCE

AUG 31 1995

TERM OF ISSUANCE

NOTICE OF PESTICIDE: REGISTRATION
 REREГИSTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

Lonza Formulation DC-800

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Lonza Inc.
17-17 Route 208
Fair Lawn, N.J. 07410

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment.

a. Add the phrase "EPA Registration No. 6836-227".

b. Delete the phrase "Lonza Formulation DC-800 is recommended for use on exhaust fans, metal ducts and filters, coils and drain pans of air conditioning and refrigeration equipment and heat pumps".

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

3. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at 703-305-6982.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

**Precautionary Statements
Hazards to Humans and Domestic
Animals**

**LONZA
FORMULATION DC-800**

CAUTION

Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Statement of Practical Treatment:

In case of contact with eyes or skin, flush eyes or skin immediately with plenty of water for at least 15 minutes. If irritation persists, get medical attention.

Storage and Disposal:

Do not contaminate water, food, or feed by storage or disposal. Do not store on side. Avoid creasing or impacting of side walls.

Container Disposal:

Triple rinse (or equivalent). Then offer for recycling, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

(For containers less than or equal to 1 gallon, use this Storage and Container Disposal statement.)

Store in area inaccessible to children. Do not reuse empty container with any product other than LONZA FORMULATION DC-800. Wrap container and put in trash.

Active Ingredients

Octyl decyl dimethyl ammonium chloride
Dioctyl dimethyl ammonium chloride
Didecyl dimethyl ammonium chloride
Alkyl (C₁₄, 50%; C₁₂, 40%; C₁₆, 10%) dimethyl benzyl amm
Inert Ingredients

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**SEE BACK/SIDE/RIGHT/LEFT
FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Registration No. 6836-
EPA Establishment No. 6836-IL-1
Net Contents

Manufactured by:
LONZA INC., 17-17 ROUTE 208, Fair Lakes, VA 22034

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

AUG 31 1995

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

6836-227

407
LONZA FORMULATION DC-800 is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1, the AIDS Virus), fungicidal, and will prevent the growth of mold and mildew and their odors when used as directed.

When used as directed, LONZA FORMULATION DC-800 will clean and deodorize surfaces in rest room and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

Cross-contamination is of major housekeeping concern, LONZA FORMULATION DC-800 has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions, and industry.

LONZA FORMULATION DC-800 delivers unsurpassed non-acid cleaning performance in an economical Ready-to-Use package. Powerful, effective, yet economical, LONZA FORMULATION DC-800 always applies the proper strength for the job with no dilution required.

LONZA FORMULATION DC-800 is a Ready-to-Use one step Hospital Use disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1, the AIDS Virus), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION DC-800 is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, health clubs and spas.

LONZA FORMULATION DC-800 is recommended for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, athletic facilities, kitchens, restaurants and bars, transportation terminals, hotels and motels.

Use LONZA FORMULATION DC-800 to clean and disinfect water and non-porous salon (barber) tools and instruments: combs, brushes, scissors, blades, and manicure instruments.

LONZA FORMULATION DC-800 is a heavy duty disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

LONZA FORMULATION DC-800 maximizes labor results by effectively controlling odors for a long lasting clean. LONZA FORMULATION DC-800 Ready-to-Use strength minimizes labor costs by eliminating the need for dilution. LONZA FORMULATION DC-800 is recommended for nonscratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

LONZA FORMULATION DC-800 is formulated for use in daily maintenance programs with a balance of detergents, biocides, and mal odor counteractants that deliver effective cleaning, disinfecting, and mal odor control.

Multi-Purpose LONZA FORMULATION DC-800 cleans, deodorizes and disinfects most washable surfaces.

LONZA FORMULATION DC-800 removes tough grease, food stains, soap scum, and ground-in dirt and grime throughout the house.

LONZA FORMULATION DC-800 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 FORMULATION DC-800 is recommended for nonscratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

LONZA FORMULATION DC-800 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, fiberglass, stone and plastic).

LONZA FORMULATION DC-800 kills household germs in minutes; effective against harmful pseudomonas, staph and strep, while effectively controlling mold and mildew.

~~LONZA FORMULATION DC-800 is recommended for use on stainless steel, metal, chrome, and fiberglass, walls and drain pans of air conditioning and refrigeration equipment and heat exchangers.~~

LONZA FORMULATION DC-800 is recommended for cleaning and disinfecting of ultrasound transducers, probes, mammography compressor plates and other inanimate hard surfaces.

LONZA FORMULATION DC-800 will not leave grit or soap scum. Will not cause swelling of transducer membrane or harm compressor plates.

LONZA FORMULATION DC-800 is a versatile multipurpose cleaner and broad spectrum disinfectant formulated for use in Ultrasonic Baths (Ultrasonic cleaning units).

LONZA FORMULATION DC-800 eliminates 99.9% of harmful Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds.

This product contains no phosphorus.

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6836-227

June 15, 1995

BEST COPY AVAILABLE

LONZA FORMULATION DC-800 is a Hospital Use Disinfectant, Bactericidal according to the AOAC Use-Dilution Test method, Virucidal* according to the virucidal qualification, Fungicidal according to the AOAC fungicidal test, modified in the presence of 400 ppm hard water plus 5% organic serum against:

Pseudomonas aeruginosa	Salmonella schottmuelleri
Staphylococcus aureus	Salmonella typhi
Staphylococcus aureus MRSA	Serratia marcescens
Salmonella choleraesuis	Shigella dysenteriae
Brevibacterium ammoniagenes	Streptococcus faecalis
Enterobacter aerogenes	Streptococcus pyogenes
Escherichia coli	Vibrio cholerae
Klebsiella pneumoniae	Trichophyton mentagrophytes (the athlete's foot fungus)
*Herpes Simplex Type I	Herpes Simplex Type II
Influenza A/Brazil	Vaccinia
HIV-1 (AIDS Virus)	
at 60 second contact	

LONZA FORMULATION DC-800 is a sanitizer for hard porous and non-porous non-food contact surfaces against:

Staphylococcus aureus Klebsiella pneumoniae

LONZA FORMULATION DC-800 is a mildewstat and will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces.

Directions for Use

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

(Instrucciones de uso)

El empleo de este producto de manera contraria a lo indicado en su etiqueta constituye una violación de la Ley Federal.)

Apply LONZA FORMULATION DC-800 to hard (inanimate) non-porous surfaces thoroughly wetting surfaces as recommended and required, with a sprayer.

(Aplicar la solución utilizable a superficies duras (inanimadas) no porosas mojando completamente las superficies según lo recomendado y requerido, con un rociador.)

For heavily soiled areas, a preliminary cleaning is required. (Remove coupling gel from transducer.)

(Para áreas muy manchadas, se requiere una limpieza preliminar.)

Rinse food contact surfaces with potable water.

(Enjuague con agua potable las superficies que contactan alimentos.)

(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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

(Este producto no debe usarse como esterilizante/desinfectante de alto nivel en ninguna superficie o instrumento que: (1) haya de introducirse directamente en el organismo humano, ya sea en la circulación sanguínea o en contacto con ésta o con zonas orgánicas normalmente estériles, o (2) haya de entrar en contacto con mucosas intactas aunque habitualmente no atraviese la barrera hematológica o no penetre de alguna otra manera en zonas normalmente estériles del organismo.)

Disinfection*Virucidal/Mold and Mildew Control directions:

(Instrucciones de desinfección/control de *virucidad/moho y enmohecimiento:)

Use a coarse spray device (trigger sprayer). Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray mist.

(Utilizer un aparato de rociado grueso. Rociar 6 a 8 pulgadas desde la superficie, frotar con un cepillo, esponja o trapo. No respirar el vapor del rociador.)

Treated surfaces must remain wet for 10 minutes.

(Las superficies tratadas deben mantenerse mojadas durante 10 minutos.)

Wipe clean with a cloth or tissue (wiper).

(Limpiar con un trapo o papel de seda.)

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6-15-95
Non-Acid Toilet Bowl Disinfectant/Cleaner directions:

Empty toilet bowl or urinal and apply to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, allow to stand for 10 minutes and flush.

(Instrucciones para el desinfectante/limpiador no ácido de inodoro:

Vaciar la taza del inodoro o orinal y aplicar a las superficies expuestas, inclusive debajo del reborde, con un trapo, estropajo, esponja o rociador, dejar estar por 10 minutos y correr el agua.)

Sanitizing directions:

Treated surfaces must remain wet for 60 seconds.

(Instrucciones de esterilización de superficies:

Las superficies tratadas deben mantenerse mojas durante 60 segundos.)

Ultrasonic Bath Disinfectant/Cleaner directions:

Use LONZA FORMULATION DC-800 to clean and disinfect hard (inanimate) non-porous objects compatible with Ultrasonic cleaning units.

Pour fresh solution directly into bath chamber. Place objects into unit and operate for a minimum of 10 minutes, according to manufacturer's use directions. For heavily soiled objects, a preliminary cleaning is required.

Remove objects and rinse with sterile water (sterile water for injection), or allow to air dry. Replace solution daily or when solution becomes visibly dirty or discolored.

Salon (Barber) Instruments and Tools Disinfection Directions:

A preliminary cleaning is required for heavily soiled instruments and tools. Completely immerse water and nonporous salon instruments and tools for 10 minutes. Rinse thoroughly and dry before use. Fresh solution should be prepared daily or more often if solution becomes cloudy or soiled.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

PELIGRO:

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

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1077
* **KILLS HIV 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 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 FORMULATION DC-800**.

CONTACT TIME: Leave surface wet for 60 seconds. Use a 10 minute contact time for disinfection against all other virus, bacteria, and fungi 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.

(* **MATA EL VIH EN SUPERFICIES/OBJECTOS EXPUESTOS AL MEDIO AMBIENTE PREVIAMENTE CONTAMINADOS CON SANGRE/LIQUIDOS CORPORALES, CUANDO SE LOS HA LIMPIADO PREVIAMENTE**, en lugares destinados al cuidado de la salud u otros lugares donde se prevea la posibilidad de contaminación de superficies/objetos inanimados con sangre o líquidos corporales y en los que dichas superficies/objetos pueden estar relacionados con el potencial de transmisión del virus de la inmunodeficiencia humana tipo (VIH-1) (asociado con el SIDA).

"INSTRUCCIONES ESPECIALES PARA LA LIMPIEZA Y DESCONTAMINACION CONTRA EL VIH-1 SOBRE SUPERFICIES/OBJECTOS CONTAMINADOS CON SANGRE/LIQUIDOS CORPORALES."

PROTECCION PERSONAL: La limpieza deberá hacerse siempre usando guantes de látex protectores, batas, máscaras y protección de la vista.

PROCEDIMIENTO DE LIMPIEZA: La sangre y otros líquidos corporales que contienen el VIH deben limpiarse completamente de las superficies y los objetos antes de aplicar **LONZA FORMULATION DC-800**.

TIEMPO DE CONTACTO: Dejar la superficie mojada durante 60 segundos. Dejar 10 minutos de tiempo contacto para la desinfección contra todos los otros virus, bacterias y hongos declarados.

ELIMINACION DE MATERIALES INFECCIOSOS: La sangre, los líquidos corporales, materiales de limpieza y ropa deben someterse al autoclave y eliminarse de acuerdo con la reglamentaciones locales sobre eliminación de desechos infecciosos.)

Approved
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in EPA Letter Dated:

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