

PM 31

6836-205

8-12-99

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

AUG 12 1999

Subject: Lonza Formulation DC-108N
EPA Registration No. 6836-205
Amendment Dated February 15, 1999

Attn: Ruth Trager
Manager, Regulatory Services

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to add two additional organisms (Staphylococcus aureus - Vancomycin resistant and Acinetobacter baumannii) to the label, is acceptable. A stamped copy of the label is enclosed for your records.

Please submit one (1) copy of the finished label before this product is released for shipment. If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL	7510W							
SURNAME	Z. Jones							
DATE	8-9-99							

LONZA FORMULATION DC-108N

Disinfectant-Cleaner-Sanitizer-Fungicide-Mildewstat-Virucide*-Deodorizer
for Hospitals, Institutional and Industrial Use
Effective in hard water up to 400 ppm hardness (Calculated as
CaCO₃) in the presence of 5% serum contamination

Active Ingredient:	
Didecyl dimethyl ammonium chloride.....	15.36%
Inert Ingredients.....	84.64%
	100.00%

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Keep out of reach of children. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT (FIRST AID)

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

(If container size is 5 gallons or greater, use the following Environmental Hazards statements.)

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge.

Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

(If container size is one gallon or less, use the following Storage and Disposal statements.)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Wrap and discard in trash.

(If container size is greater than one gallon, use the following Storage and Disposal statements.)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Store in original container in areas inaccessible to children. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

(For Metal containers:)

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

(For Plastic containers:)

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

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO

SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

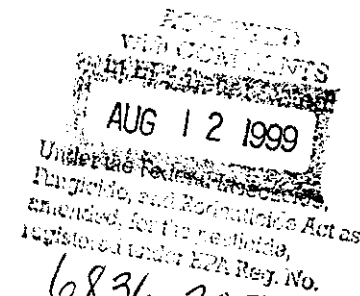
EPA Reg. No. 6836-205

EPA Est. No. 6836-IL-1

Net Contents _____

Manufactured by:

LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410



20/10

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. **LONZA FORMULATION DC-108N** has been formulated to aid in the reduction of cross-contamination in these areas.

LONZA FORMULATION DC-108N 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 FORMULATION DC-108N is an effective one-step sanitizer-cleaner for use on non-food contact surfaces. When used as directed, **LONZA FORMULATION DC-108N** 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 FORMULATION DC-108N 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.

LONZA FORMULATION DC-108N is recommended for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels. For use in households. This product contains no phosphorous.

LONZA FORMULATION DC-108N is a no-rinse neutral pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

LONZA FORMULATION DC-108N can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

LONZA FORMULATION DC-108N provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to recoat.

LONZA FORMULATION DC-108N maximizes labor results by effectively controlling odors.

LONZA FORMULATION DC-108N Cleans, shines, deodorizes and disinfects all hard nonporous household surfaces. Inhibits the growth mold and mildew, leaving bathrooms & kitchens clean and smelling fresh.

LONZA FORMULATION DC-108N is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

LONZA FORMULATION DC-108N is for use in kitchens, bathrooms and other household areas.

LONZA FORMULATION DC-108N kills household germs in 10 minutes; effective against harmful pseudomonas, staph and strep, Influenza A/PR and athlete's foot fungus.

LONZA FORMULATION DC-108N is a neutral pH multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors, and other glass surfaces.

Use **LONZA FORMULATION DC-108N** on the multi-touch surfaces responsible for cross-contamination.

Use **LONZA FORMULATION DC-108N** on finished floors, high speed burnished floors, conductive flooring, tables, chairs, bathroom bowls, basins, countertops, bed rails, door knobs and handles, glass surfaces including windows and mirrors.

LONZA FORMULATION DC-108N is recommended for Poultry Premise Sanitation (Hatcheries):

Egg Receiving Area	Tray Dumping Area	Chick Processing Area
Egg Holding Area	Chick Holding Room	Chick Loading Area
Setter Room	Hatchery Room	Poultry Buildings

LONZA FORMULATION DC-108N is recommended for Swine Premise Sanitation:

Farrowing Barns and Areas	Dressing Plants	Blocks
Waterers and Feeders	Loading Equipment	Creep Area
Hauling Equipment	Nursery	Chutes

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 12 1999

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

6836-205

LONZA FORMULATION DC-108N is a Hospital Disinfectant at 1/2 ounce per gallon (4 milliliters per liter, 1:256 dilution), modified in the presence of 250 ppm hard water, and at 2/3 ounce per gallon (5 milliliters per liter, 1:200 dilution), modified in the presence of 400 ppm hard water. **LONZA FORMULATION DC-108N** is Bactericidal according to the AOAC Use-Dilution Test method, Virucidal* according to the virucidal qualification on hard inanimate surfaces, Fungicidal according to the AOAC fungicidal test, modified in the presence of 5% organic serum against:

Pseudomonas aeruginosa	Proteus vulgaris
Salmonella choleraesuis	Salmonella schottmuelleri
Staphylococcus aureus	Salmonella typhi
Acinetobacter baumannii	
Brevibacterium ammoniagenes	Salmonella typhimurium
Chlamydia psittaci	Serratia marcescens
Enterobacter aerogenes	Shigella dysenteriae
Enterobacter cloacae	Shigella flexneri
Enterococcus (Streptococcus) faecalis	Shigella sonnei
Escherichia coli	Staphylococcus epidermidis
Klebsiella pneumoniae	Streptococcus pyogenes

Escherichia coli - Methicillin resistant
 Enterococcus (Streptococcus) faecalis (Vancomycin-resistant) (VRE)
 Enterococcus (Streptococcus) faecalis-(Methicillin-resistant)
 Klebsiella pneumoniae - Methicillin resistant
 Staphylococcus aureus - Methicillin resistant (MRSA)
 Staphylococcus aureus - Vancomycin resistant (VRSA)

Aspergillus niger	Candida albicans
Trichophyton mentagrophytes	
HIV-1 (AIDS virus)	Herpes Simplex Type 2
Influenza A/PR	Rubella
Herpes Simplex Type 1	Vaccinia

LONZA FORMULATION DC-108N is a sanitizer for hard nonporous non-food contact surfaces at 1/2 - 2/3 ounces per gallon (4-5 milliliters per liter) against:

Enterobacter aerogenes	Staphylococcus aureus
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Directions for Use

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

(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.)

Preparation of use-solution:

For water hardness up to 250 ppm add 1/2 ounce per gallon (4 milliliters per liter) of water (1:256) and for water hardness up to 400 ppm add 2/3 ounce per gallon (5 milliliters per liter) of water (1:200), to disinfect hard, nonporous surfaces.

For heavy duty use, add 2 ounces per gallon (64 milliliters per liter) of water (1:64), to disinfect hard, nonporous surfaces.

ACCEPTED
 with COMMENTS
 AUG 12 1999
 Under the Federal Food, Drug, and Cosmetic Act as amended, for the purpose of registration under FDCA, Reg. 201
 6836-205

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Disinfection/Virucidal/Mold and Mildew Control directions:

Apply **use-solution** to hard (inanimate) nonporous surfaces thoroughly wetting surfaces with a cloth, mop, sponge, or sprayer.

For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray.

Disinfection/Virucidal directions:

Add 1/2 ounce per gallon of water, to disinfect hard, nonporous surfaces. Treated surfaces must remain wet for 10 minutes (2 minutes for disinfection against all viruses claimed). Prepare a fresh solution daily or when use solution becomes diluted or soiled.

Mold and Mildew Control directions:

Add 1/2 ounce per gallon of water, to control the growth of mold and mildew and their odors on hard, nonporous 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:

Add 1/2 - 2/3 ounce per gallon (4-5 milliliters per liter) of water, to sanitize hard nonporous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

***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-108N**.

CONTACT TIME: Leave surface wet for 2 minutes with 1/2 ounce per gallon (4 milliliters per liter) **use-solution**. Use a 10 minute contact time for disinfection against all other 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.

Non-Acid Toilet Bowl Disinfectant/Cleaner directions:

From concentrate:

Add 1/2 - 2/3 ounce (15-20 milliliters) 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 1/2 - 2/3 ounce per gallon (4-5 milliliters per liter) **use-solution** to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, allow to stand for 10 minutes and flush.

For Heavy-duty use:

Empty toilet bowl or urinal and apply (2 ounces per gallon, 16 milliliters per liter) **use-solution** to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, allow to stand for 10 minutes and flush.

Glass Cleaning/Deodorizing Directions:

Add (0.25-1 ounce per gallon, 2-8 milliliters per liter) of water to clean and deodorize windows, mirrors, and glass surfaces.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:
AUG 12 1999
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, hereby certified
Registration Number 6836-205

Soft

POULTRY (and SWINE) PREMISE SANITATION

SITE PREPARATION

The first step in any on-going sanitation program should be the removal of gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, disinfection can be accomplished in one easy step.

CLEANING AND DISINFECTION

For all general cleaning and disinfection, use 1/2 - 2/3 ounce of **LONZA FORMULATION DC-108N** per gallon of water (1:256 solution). Apply **LONZA FORMULATION DC-108N** using a cloth, mop, or pressure sprayer so as to thoroughly wet surface to be disinfected. Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a precleaning step is required. Prepare a fresh solution after each use.

APPLICATIONS AND USE DILUTION

POULTRY (and SWINE) PREMISE

Remove all animals and feeds from premises, trucks, coops, and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 1/2 - 2/3 ounce of **LONZA FORMULATION DC-108N** per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. 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.

HATCHERIES: Use 1/2 - 2/3 ounce of **LONZA FORMULATION DC-108N** per gallon of water to treat hatches, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

VEHICLES: Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and **LONZA FORMULATION DC-108N**. Use 1/2 - 2/3 ounce per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

SHOE BATHS: Shoe baths containing one inch of freshly made disinfectant solution should be placed at all entrances to buildings and hatcheries. Change the disinfectant solution in the bath daily or when solution appears dirty.

DRESSING PLANT USE: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the recommended use solution 1/2 ounce per gallon. Scrub to loosen all soils. Allow to soak for 10 minutes and thoroughly rinse all wetted and cleaned surfaces with potable water.

SANITIZING HATCHERY ROOMS USING FOGGING DEVICES

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix one part **LONZA FORMULATION DC-108N** to five parts water (1/2 gallons **LONZA FORMULATION DC-108N** to 2.5 gallons water). Insert the nozzle of the fogger through a suitable opening into the room. With the setting in maximum output, fog for one minute for each 4000 cubic feet of space in the room.

SANITIZING INCUBATORS AND HATCHERS USING FOGGING DEVICES

Mix 6 ounces **LONZA FORMULATION DC-108N** to 122 ounces water. Fog 3-8 ounces of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers. Discontinue hatcher treatments at least 24 hours prior to pulling the hatch. Do not allow people to contact or breath this fog and do not enter until the fog has settled (30-60 minutes after fogging is completed). It is acceptable to fog setters and hatchers with a 1/2 - 2/3 ounce per gallon solution of **LONZA FORMULATION DC-108N** on an hourly or every other hour basis. If this is done, fog for 30-90 seconds once per hour or once every two hours. When fogging is completed, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

NOTE: The fog generated is irritating to the eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTING OR ROOM AND MACHINE SURFACES.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 12 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6136-205

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