

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

MAY 18 2000

Subject: Lonza DC-109N
 EPA Registration No. 6836-206
 Amendment Dated November 15, 1999

Attn: Wendy A. McCombie
 Agent for Lonza, Inc.

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. Please refer to the labeling changes listed below.

1. Changes made to the label include additional statements in the Precautionary language to bring it in accord with the Agency Review Manual. Also, added were revisions to the "Disinfection Directions" to include fungicidal use and the need to use a potable water rinse following treatment of surfaces that may come in contact with food. Separate directions were added for food processing plants and food storage areas. The scent descriptions were also added to the label. These revisions are acceptable.
2. On page 2, first paragraph, revise "Lonza Formulation DC-110N has been formulated to aid in the reduction of cross-contamination in these areas", to read "Lonza Formulation DC-110N has been formulated to aid in the reduction of cross-contamination from treated surfaces in these areas".
3. On page 2, right side, revise "effective against harmful pseudomonas, staph and strep, Influenza A/PR and athlete's foot fungus, to read "effective against harmful Pseudomonas aeruginosa (ATCC), Staphylococcus aureus (ATCC), saph, Streptococcus pyogenes (ATCC), strep germsTriphophyton mentagrophytes (ATCC), athlete's foot fungus". The common names must be qualified with the complete nomenclature and ATCC designation.
4. The following comment should be added on page 2 to the third statement, right side that says that the product "is for use in kitchens, bathrooms and other household areas": Food contact surfaces such as countertops should be rinsed with potable water following treatment and prior to use.

CONCURRENCES

5. Under "Storage and Disposal", the heading, "Pesticide Storage or Storage" needs to be added							
SYMBOL	75-10W						
SURNAME	B. Jones						
DATE	5-1-2000						

preceding the "Pesticide Disposal" section with the following statements, "Open dumping is prohibited" and "Store in original container in areas accessible to children." Also, the statement, "Do not reuse empty container," should appear as the first sentence under the "Container Disposal" instructions.

6. The site, institutions, is too broad.

7. The "Disinfection" heading should be revised by replacing "Mold and Mildew Control" with "Fungicidal."

8. Since this product may be used as a disinfectant in food contact areas, you will need to address the following comments:

A. *Food Processing Plants: You will need to either add the disclaimer statement, "Do not use on food contact/processing surfaces" or state "Before using this product, food products and packaging materials must be removed from the room or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water."

9. You should remove "Glass" from the "Cleaning/Deodorizing" directions because this product may be used on all the hard, non-porous surfaces listed on this label, including glass.

10. The disinfection, non-food contact sanitizer, and poultry/swine premise (includes hatcheries, vehicles, shoe baths, and dressing plants) directions need to indicate whether the use-dilution should be allowed to air dry or be removed by wiping after the allotted contact time.

11. The combined "Cleaning/Disinfection" directions are inappropriate for poultry and swine premise sanitation because these sites must be thoroughly cleaned with soap/detergent before the surfaces are disinfected. (Refer to DIS/TSS 18 and 19)

12. Shoe Baths: You will need to add the following statements and modify the contact time based on efficacy claim: Scrape waterproof work boots and place in a 2.3 oz per gallon of water solution for 60 seconds or 10 minutes prior to entering the area.

13. Hatchery Room Sanitation:

A. The sentence, "Thoroughly scrub treated troughs, racks, other feeding and watering appliances with soap or detergent and rinse with potable water," should be moved to the end of this paragraph.

B. The statements "When fogging is complete, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried," should appear after the "...one minute for each 4000 cubic feet of space in room" statement.

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)

LONZA FORMULATION DC-109N

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

Fresh clean scent / Lemon scent / Pine Scent / Mint scent / Floral scent / Citrus scent

Active Ingredient:
Didecyl dimethyl ammonium chloride 7.68%
Inert Ingredients 92.32%
Total: 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO

SEE SIDE / LEFT / RIGHT / BACK PANEL FOR
PRECAUTIONARY STATEMENTS AND FIRST AID

EPA Reg. No. 6836-206

EPA Est. No. (as noted on the container)

Net Contents (as noted on the container)

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

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves when handling. May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT (FIRST AID)

IF IN EYES: Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol.

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.

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Cross-contamination is of major housekeeping concern not only in hospitals, but also in schools, institutions, and industry. **LONZA FORMULATION DC-109N** has been formulated to aid in the reduction of cross-contamination in these areas.

LONZA FORMULATION DC-109N 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-109N is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, **LONZA FORMULATION DC-109N** 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-109N 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-109N 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-109N is a no-rinse neutral pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

LONZA FORMULATION DC-109N can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

LONZA FORMULATION DC-109N 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-109N improves labor results by effectively controlling odors.

LONZA FORMULATION DC-109N Cleans, shines, deodorizes and disinfects hard nonporous household surfaces. Inhibits the growth mold and mildew, leaving bathrooms & kitchens clean and smelling fresh.

LONZA FORMULATION DC-109N is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

LONZA FORMULATION DC-109N is for use in kitchens, bathrooms and other household areas.

LONZA FORMULATION DC-109N kills household germs in 10 minutes; effective against harmful pseudomonas, staph and strep, Influenza A/PR and athlete's foot fungus.

LONZA FORMULATION DC-109N is a neutral pH multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors, and other glass surfaces.

Use **LONZA FORMULATION DC-109N** on the multi-touch surfaces responsible for cross-contamination.

Use **LONZA FORMULATION DC-109N** on finished floors, high speed burnished floors, conductive flooring, washable walls, tables, chairs, bathroom bowls, sinks, basins, shower stalls, tubs, tiles, toilets, countertops, stove tops, appliances, refrigerators, cabinets, garbage cans, tables, outdoor furniture, chairs, desks, telephones, door knobs and handles, and glass surfaces including windows and mirrors.

LONZA FORMULATION DC-109N 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-109N is recommended for Swine Premise Sanitation:

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

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LONZA FORMULATION DC-109N is a Hospital Disinfectant at 1 ounce per gallon (8 milliliters per liter, 1:128 dilution), modified in the presence of 250 ppm hard water, and at 1-1/3 ounces per gallon (10 milliliters per liter, 1:100 dilution), modified in the presence of 400 ppm hard water.

LONZA FORMULATION DC-109N 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
Salmonella choleraesuis
Staphylococcus aureus
Acinetobacter baumannii
Brevibacterium ammoniagenes
Chlamydia psittaci
Enterobacter aerogenes
Enterobacter cloacae
Enterococcus (Streptococcus) faecalis
Escherichia coli
Klebsiella pneumoniae

Proteus vulgaris
Salmonella schottmuelleri
Salmonella typhi

Salmonella typhimurium
Serratia marcescens
Shigella dysenteriae
Shigella flexneri
Shigella sonnei
Staphylococcus epidermidis
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 Intermediate Resistant (VISA)

Aspergillus niger
Trichophyton mentagrophytes

Candida albicans

*HIV-1 (AIDS virus)
*Influenza A/PR
*Herpes Simplex Type 1

*Herpes Simplex Type 2
*Rubella
*Vaccinia

LONZA FORMULATION DC-109N is a sanitizer for hard nonporous non-food contact surfaces at 1 - 1-1/3 ounces per gallon (8 - 10 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 ounce per gallon (8 milliliters per liter) of water (1:128).

For water hardness up to 400 ppm add 1-1/3 ounce per gallon (10 milliliters per liter) of water (1:100), to disinfect hard, nonporous surfaces.

For heavy duty use, add 4 ounces per gallon (32 milliliters per liter) of water (1:32), to disinfect hard, nonporous surfaces.

Disinfection / *Virucidal / Fungicidal 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.

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.

Rinse all surfaces which come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. This product should not be used to clean utensils, glassware and dishes.

Mold and Mildew Control directions:

To control the growth of mold and mildew and their odors on hard, nonporous surfaces, apply use-solution to thoroughly wet all treated surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappears.

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Sanitizing Non-Food Contact Surface directions:

Add 1 - 1-1/3 ounces per gallon (8 - 10 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-109N**.

CONTACT TIME: Leave surface wet for 2 minutes with a 1 ounce per gallon (8 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 - 1-1/3 ounce (30 - 40 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 - 1-1/3 ounces per gallon (8 - 10 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 4 ounces per gallon (32 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 1/2 - 2 ounces per gallon (4 - 16 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.

Directions for Food Processing Plants:

For use on non-food contact surfaces such as floors, walls, tables, garbage cans and disposal areas: Follow disinfection directions.

Directions for Food Storage Areas:

For use on non-food contact surfaces such as shelves, floors, walls and tables: Before using this product, food products and packaging materials must be removed from the room or carefully protected. Then follow disinfection directions.

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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 - 1-1/3 ounce of **LONZA FORMULATION DC-109N** per gallon of water (1:128 solution). Apply **LONZA FORMULATION DC-109N** 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 - 1-1/3 ounce of **LONZA FORMULATION DC-109N** 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 - 1-1/3 ounces of **LONZA FORMULATION DC-109N** per gallon of water to treat hatchers, 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-109N** Use 1 - 1-1/3 ounces per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

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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 of 1 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.

→ Same use dilution
1 - 128oz

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 two parts **LONZA FORMULATION DC-109N** to five parts water (1 gallon of **LONZA FORMULATION DC-109N** 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 12 ounces **LONZA FORMULATION DC-109N** 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 - 1-1/3 ounces per gallon solution of **LONZA FORMULATION DC-109N** 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 OF ROOM AND MACHINE SURFACES.

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