

PM 31

6836-206

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 15 1997

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

Attention: Eliot I. Harrison

Subject: Lonza Formulation DC-109N
EPA Registration Number 6836-206
Your Submission Dated December 31, 1996
EPA Received Date January 17, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add a claim against Vancomycin-resistant Enterococcus (Streptococcus) faecalis, is acceptable.

The submitted efficacy data developed by the AOAC Use-Dilution Test Method appear adequate to support the effectiveness of the product as a disinfectant against Enterococcus faecalis-Vancomycin Resistant on hard, non-porous surfaces in a 1:64 dilution in the presence of 400 ppm AOAC hard water and 5% serum load for a contact time of ten minutes at 20 degrees Celsius.

A stamped copy of labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely yours,

Marshall Swindell
Acting Product Manager(31)
Antimicrobial Program Branch
Registration Division(7505W)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

STATEMENT OF PRACTICAL TREATMENT

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.

Precautionary Statements

Hazards to Humans and Domestic Animals

DANGER. 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.

ENVIRONMENTAL HAZARDS

(containers greater than 5 gallons)

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.

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 mixture or 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

(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. (Plastic containers greater than 1 Gallon) 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. (1 Gallon or less) Wrap and discard in trash.

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

Active Ingredient

Didecyl dimethyl ammonium chloride 7.68%

Inert Ingredients

..... 92.32%
100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO

SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

EPA Registration No.
EPA Establishment No.
Net Contents

6836-206
6836-IL-1

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

ACCEPTED
WITH COMMENTS
IN EPA Letter dated

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Cross-contamination is of major housekeeping concern not only in hospitals, but 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 maximizes labor results by effectively controlling odors.

LONZA FORMULATION DC-109N Cleans, shines, deodorizes and disinfects all hard non-porous 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, tables, chairs, bathroom bowls, basins, countertops, bed rails, door knobs and handles, 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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Disinfection/Virucidal/Mold and Mildew Control directions:

Apply use-solution to hard (inanimate) non-porous surfaces thoroughly wetting surfaces as recommended and required, 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 mist.

Disinfection/Virucidal directions:

Add 1 ounce per gallon of water, to disinfect hard, non-porous 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 ounce per gallon of water, to control 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:

Add 1 - 1 1/3 ounces per gallon (8-10 milliliters per liter) of water, to sanitize hard non-porous 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 (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 ounces (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 0.5-2 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 mist.

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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 ounces of LONZA FORMULATION DC-109N per gallon of water (1:128/1:100 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 ounces 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. Rinse with a potable water rinse before reuse.

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.

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 of LONZA FORMULATION DC-109 per gallon of water. 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 two parts LONZA FORMULATION DC-109N to five parts water (1 gallon 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.