

6836-267

9-5-2001

1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

Subject: Lonza Formulation DCN 400-256  
EPA Registration No. 6836-267  
Amendment Date: June 6, 2001  
EPA Receive Date: June 7, 2001

SEP 05 2001

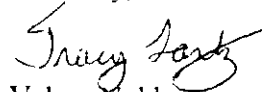
Attention: Ms. Christina Swick  
Agent

The amendment, referenced above, submitted in connection with registration under FIFRA sec. sec. 3(c)(7)(A) to add additional organisms and to revise first aid statements per PR Notice 2001-1 is acceptable provided you address the following comments before this product is released for shipment.

On page 2, second column, seventh paragraph, you need to qualify "tiles" as a hard, non-porous surface by stating "glazed tiles."

A stamped copy of the label is enclosed. Please submit one (1) copy of the final printed label to the Agency before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

*for* 

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

2/7

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Corrosive. Causes irreversible eye damage and skin burns. Harmful if absorbed through skin and / or swallowed. Harmful if inhaled. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves. Avoid breathing vapor (spray mist). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID**

Call a poison control center or doctor for treatment advice. Have the container or label with you when calling a poison control center or doctor, or going for treatment.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

**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.

**LONZA FORMULATION  
DCN 400-256**

Disinfectant - Cleaner - Sanitizer - Fungicide Mildewstat -  
Virucide\* - Deodorizer  
for Hospitals, Institutional and Industrial Use

Effective in hard water up to 400 ppm hardness (Calculated as CaCO<sub>3</sub>) in the presence of 5% serum contamination

Fresh / Clean / Lemon / Pine / Mint / Floral / Citrus  
(scent) (fragrance) (scented) (odor)

Formulated for effective poultry premise sanitation  
Formulated for effective swine premise sanitation

Active Ingredient:	
Didecyl dimethyl ammonium chloride.....	20.48%
Inert Ingredients:.....	79.52%
Total.....	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER PELIGRO**

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

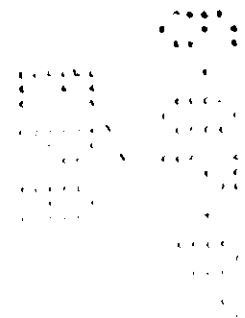
EPA Reg. No. 6836-267  
EPA Est. No. (as noted on the container)  
Net Contents (as noted on the container)

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

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

**SEP 05 2001**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
registered under EPA Reg. No. **6836-267**



Cross-contamination is of major housekeeping concern not only in hospitals, but also in schools, institutions, and industry. **LONZA FORMULATION DCN 400-256** has been formulated to aid in the reduction of cross-contamination from treated surfaces in these areas.

**LONZA FORMULATION DCN 400-256** a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal\* (including HIV-1 and HBV), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

**LONZA FORMULATION DCN 400-256** is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, **LONZA FORMULATION DCN 400-256** will deodorize surfaces in restrooms 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.

**LONZA FORMULATION DCN 400-256** 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.

Use **LONZA FORMULATION DCN 400-256** 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 DCN 400-256** is a no-rinse neutral pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

**LONZA FORMULATION DCN 400-256** can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

**LONZA FORMULATION DCN 400-256** provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to recoat.

**LONZA FORMULATION DCN 400-256** improves labor results by effectively controlling odors.

**LONZA FORMULATION DCN 400-256** cleans, shines, deodorizes and disinfects hard nonporous household surfaces. Inhibits the growth mold and mildew, leaving bathrooms & kitchens clean and smelling fresh.

Use **LONZA FORMULATION DCN 400-256** for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

Use **LONZA FORMULATION DCN 400-256** in kitchens, bathrooms and other household areas.

**LONZA FORMULATION DCN 400-256** kills household germs; effective against harmful Pseudomonas aeruginosa (Pseudomonas), Staphylococcus aureus (Staph) and Streptococcus faecalis (Strep), influenza A/PR and Trichophyton mentagrophytes (Athlete's foot fungus).

**LONZA FORMULATION DCN 400-256** is a neutral pH multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors, and other glass surfaces.

Use **LONZA FORMULATION DCN 400-256** on the multi-touch surfaces responsible for cross-contamination.

Use **LONZA FORMULATION DCN 400-256** 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 DCN 400-256** 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 DCN 400-256N** is recommended for Swine Premise Sanitation:

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 05 2001

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 6836-267

4/7

LONZA FORMULATION DCN 400-256 is a Hospital Disinfectant at 1/2 oz. per gallon (4 milliliters per liter, 1:256 dilution), modified in the presence of 400 ppm hard water.

LONZA FORMULATION DCN 400-256 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	Salmonella typhimurium
Brevibacterium ammoniagenes	Serratia marcescens
Chlamydia psittaci	Shigella dysenteriae
Enterobacter aerogenes	Shigella flexneri
Enterobacter cloacae	Shigella sonnei
Enterococcus (Streptococcus) faecalis	Staphylococcus epidermidis
Escherichia coli	Streptococcus pyogenes
Klebsiella pneumoniae	

Escherichia coli - Methicillin resistant  
 Enterococcus 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  
 Candida albicans  
 Trichophyton mentagrophytes

- \*Hepatitis B Virus (HBV)
- \*Herpes Simplex Type 1
- \*Herpes Simplex Type 2
- \*HIV-1 (AIDS virus)
- \*Influenza A/PR
- \*Rubella
- \*Vaccinia

LONZA FORMULATION DCN 400-256 is a sanitizer for hard nonporous non-food contact surfaces at 1/2 oz. per gallon (4 milliliters per liter) against:

Enterobacter aerogenes	Staphylococcus aureus
------------------------	-----------------------

**DIRECTIONS FOR USE:**

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

*(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used.)*

(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.)

*(or)*

This product is not for use on medical device surfaces.

**Preparation of use-solution:**

For water hardness up to 400 ppm add 1/2 oz. per gallon (4 milliliters per liter) of water (1:256), to disinfect hard, nonporous surfaces.

For heavy duty use, add 2 oz. per gallon (16 milliliters per liter) of water (1:64), to disinfect hard, nonporous surfaces.

**DISINFECTION / VIRUCIDAL / FUNGICIDAL DIRECTIONS:**

Apply use-solution to hard 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 except HBV). Wipe dry with a clean cloth or sponge or allow to air dry. Prepare a fresh solution daily or more often if use solution becomes diluted or soiled.

Rinse all surfaces that 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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 05 2001

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 6836-267

**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.

**KILLS HIV AND HBV 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) or Hepatitis B Virus (HBV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV 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 or HBV must be thoroughly cleaned from surfaces and objects before application of LONZA FORMULATION DCN 400-256.

**Contact time:** Leave surface wet for 2 minutes for HIV-1 and 10 minutes for HBV. 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 AND URINAL DISINFECTANT / CLEANER DIRECTIONS:**

**From concentrate:**

Add 1/2 oz. (15 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 oz per gallon (4 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 oz. 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 oz. per gallon (2 - 8 milliliters per liter) of water to clean and deodorize windows, mirrors, and glass surfaces.

For sprayer applications, 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.

**DIRECTIONS FOR RESTAURANTS, CAFETERIAS, BARS:**

Rinse all surfaces which come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use this product to disinfect utensils, glassware and dishes

**DIRECTIONS FOR SANITIZING NON-FOOD CONTACT SURFACES:**

Add 1/2 oz per gallon (4 milliliters per liter) of water, to sanitize hard nonporous surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 05 2001

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

6836-267

6/7

**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:**

For all general cleaning use 1/2 oz. of **LONZA FORMULATION DCN 400-256** per gallon of water. Apply with a cloth, mop, or pressure sprayer so as to thoroughly wet surfaces. Wipe or allow to air dry.

**DISINFECTION:**

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 oz. of **LONZA FORMULATION DCN 400-256** per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. 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.

Prepare a fresh solution after each use.

**HATCHERIES:** Use 1/2 oz. of **LONZA FORMULATION DCN 400-256** 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. Wipe or allow to air dry.

**VEHICLES:** Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and **LONZA FORMULATION DCN 400-256** Use 1/2 oz. per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more. Wipe or allow to air dry.

**SHOE BATH SANITIZER DIRECTIONS:** To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a 1/2 oz. per gallon of water solution for 60 seconds prior to entering area. Wipe or allow to air dry. Change the solution in the bath daily or more often if the when solution appears diluted or soiled.

**DRESSING PLANT DISINFECTION DIRECTIONS:** 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 a 1/2 oz. per gallon use solution. Scrub to loosen all soils. Allow to soak for 10 minutes and thoroughly rinse all wetted and cleaned surfaces with potable water. Wipe dry with a clean cloth or sponge or allow to air dry.

**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 DCN 400-256** to five parts water (1/2 gallon of **LONZA FORMULATION DCN 400-256** to 2 1/2 gallons of 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. 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.

**SANITIZING INCUBATORS AND HATCHERS USING FOGGING DEVICES**

Mix 6 oz. of **LONZA FORMULATION DCN 400-256** to 122 oz. of water. Fog 3 - 8 oz. 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 oz. per gallon solution of **LONZA FORMULATION DCN 400-256** 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.

**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:

SEP 05 2001

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 6836-267

2/7

(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.

**PESTICIDE STORAGE**

Open dumping is prohibited. Store in original container in areas inaccessible to children.

**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**

Do not reuse empty container

(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.

(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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 05 2001

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 6836-267