
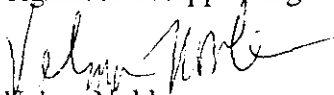


6836-268

2-11-2000

1/9

 <p style="text-align: center;">U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 401 "M" St. S.W. Washington, D.C. 20460</p> <p style="text-align: center;">NOTICE OF PESTICIDE: <u> x </u> Registration <u> </u> Reregistration</p> <p>(under FIFRA, as amended)</p>	EPA Reg. Number: 6836-268	Date of Issuance: FEB 11 2000
	Term of Issuance: Conditional	
	Name of Pesticide Product: Lonza Formulation DCN 400-128	
Name and Address of Registrant (include ZIP Code): Lonza Inc. 17-17 Route 208 Fair Lawn, NJ 07410		
<p>Note: Changes in labeling 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 EPA registration number.</p>		
<p>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.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the 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.</p> <p style="text-align: center;">This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 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 following label changes: <ol style="list-style-type: none"> a. Revise the EPA Registration Number to read, "EPA Reg. No. 6836-268". <p>The proposed product is "substantially similar" in use and composition to Lonza Formulation DC 109N, EPA Reg. No. 6836-206. However, 6836-206's label has not been updated to meet today's standards. Since this is a new registration, we are applying our current labeling standards to your application and requiring several label changes.</p>		
Signature of Approving Official:  Velma Noble Product Manager 31 Regulatory Management Branch I Antimicrobials Division (7510C)	Date: FEB 11 2000	

Page 1:

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

Page 2:

- a. 4th claim: the site, institutions, is too broad.
- b. 12th claim: when you list organisms which are killed by this product, you must always use the organism's complete scientific name, genus and species, which may be followed by shortened/abbreviated name in parenthesis. For example, "*Pseudomonas aeruginosa (Pseudomonas)*". You may not use the abbreviated name alone.

Page 4:

- a. The "Disinfection" heading should be revised by replacing "Mold and Mildew Control" with "Fungicidal."
- b. Since this product may be used as a disinfectant in food contact areas, you will need to address the following comments:

*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."

*Restaurants, Cafeterias, Bars, etc: You must recommend using a potable rinse on specific food contact surfaces such as "counters, tables, picnic tables, appliances, and or stovetops." Also, the disclaimer statement should be added: "This product is not for use to disinfect or clean utensils, glassware, and dishes."

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

Page 5:

- a. 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)
- b. Under Hatcheries, You will need to add the statement, "Rinse with potable water before reuse."
- c. Shoe Baths
 - 1. You will need to indicate which efficacy claim you want to use for these directions, disinfection or sanitization.
 - 2. Then, 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 1/2 oz. per gallon of water solution for 60 seconds or 10 minutes prior to entering area.
- d. Hatchery Room Sanitization:

* 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 this paragraph.

* 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.

3. Acute Toxicology

You have proposed to fulfill these data requirements by using the "cite-all" method of support. There does not appear to be an acceptable inhalation study for use in supporting this application. Due to this fact, the following Acute Toxicity profile is being assigned for this product. Alternately, you may submit an acute inhalation study for review by the Agency. Be advised that an inhalation study may be required at the time of Reregistration.

Acute Oral	III
Acute Dermal	III
Acute Inhalation	III
Primary Eye Irritation	I
Primary Skin Irritation	I
Dermal Sensitization	Non-Sensitizer

Precautionary Statements Revisions:

Corrosive. Cause irreversible eye damage and skin burns. Harmful if absorbed through skin or/and swallowed. Harmful if inhaled. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, faceshield, 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 before reuse.**

Statements of Practical Treatment Revisions:

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

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

IF SWALLOWED: Call a physician or get medical attention. Drink large quantities of water. Avoid alcohol.

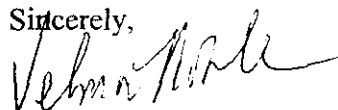
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

4. Submit two (2) copies of the revised final printed label for the record.

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

A stamped copy of the label is enclosed for your records. If you have any questions regarding this submission, you should contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



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

LONZA FORMULATION DCN 400-128

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 Ingredients

Didecyl dimethyl ammonium chloride 10.24%

Inert Ingredients 92.32%

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

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 container and put 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 use the following statements:)

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 greater than 1 Gallon use the following statements:)

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 Registration No. 6836-*EAI*

EPA Establishment No. 6836-IL-1

Net Contents _____

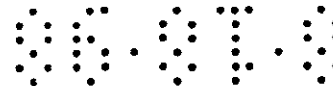
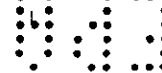
Manufactured by:

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 17 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-268



LONZA FORMULATION DCN 400-128 is a Hospital Use Disinfectant at 1 ounce per gallon (8 milliliters per liter, 1:128 dilution), modified in the presence of 400 ppm hard water. **LONZA FORMULATION DCN 400-128** 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
Staphylococcus aureus (Methicillin resistant, MRSA)	Salmonella typhimurium
Brevibacterium ammoniagenes	Serratia marcescens
Chlamydia psittaci	Shigella dysenteriae
Enterobacter aerogenes	Shigella flexneri
Enterobacter cloacae	Shigella sonnei
Escherichia coli	Staphylococcus epidermidis
Escherichia coli (Methicillin resistant)	Streptococcus faecalis
Klebsiella pneumoniae	Streptococcus faecalis
Klebsiella pneumoniae (Methicillin resistant)	(Methicillin resistant)
Pseudomonas cepacia	Enterococcus (Streptococcus)
	faecalis (Vancomycin resistant)
	Streptococcus pyogenes

Aspergillus niger
Candida albicans
Trichophyton mentagrophytes

*
HIV-1 (AIDS virus)
Influenza A/PR
Herpes Simplex Type 1
Herpes Simplex Type 2
Rubella
Vaccinia

LONZA FORMULATION DCN 400-128 is a sanitizer for hard non-porous non-food contact surfaces at 1 ounce per gallon (8 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:

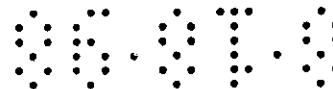
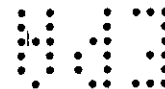
For water hardness up to 400 ppm add 1 ounce per gallon (8 milliliters per liter) of water (1:128), to disinfect hard, nonporous surfaces.

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

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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 mist.

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, 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 ounces per gallon (8 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 DCN 400-128.

CONTACT TIME: Leave surface wet for 2 minutes. 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 ounce (30 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 ounce per gallon (8 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.

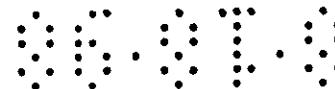
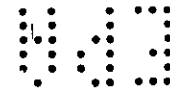
Use a coarse spray device. Spray 6-8 inches from surface, rub with sponge or cloth. Do not breathe spray mist.

ACCEPTED
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6836-268



8/9

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 ounce of LONZA FORMULATION DCN 400-128 per gallon of water (1:128 solution). Apply LONZA FORMULATION DCN 400-128 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 ounce of LONZA FORMULATION DCN 400-128 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 ounce of LONZA FORMULATION DCN 400-128 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 DCN 400-128. Use 1 ounce 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 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.

SANITIZING HATCHERY ROOMS USING FOGGING DEVICES

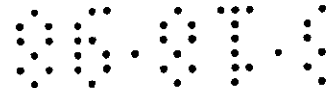
Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix two parts LONZA FORMULATION DCN 400-128 to five parts water (1 gallon LONZA FORMULATION DCN 400-128 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 DCN 400-128 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 ounce per gallon solution of LONZA FORMULATION DCN 400-128 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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