

6836-204

10/14

MAR -3 2011

Ms. Joanna Holcombe
Lonza Inc.
90 Boroline Road
Allendale. NJ 07401

SUBJECT: Lonza Formulation DC-110N
EPA Registration Number: 6836-204
Application Dated: February 09, 2011
Receipt Date: February 11, 2011

Dear Ms. Holcombe:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- To update Storage and Disposal language per PR Notice 2007-4.
- To add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1.

Based on a review of the submitted information, this notification is acceptable. A copy has been inserted in your file for future reference.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,



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

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

20914

| | | |
|--|---|------------------------------|
| <p>EPA Environmental Protection Agency Washington, DC 20460</p> | <p>United States <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other</p> | <p>OPP Identifier Number</p> |
|--|---|------------------------------|

Application for Pesticide - Section I

| | | |
|---|--|---|
| <p>1. Company/Product Number 6836-204</p> | <p>2. EPA Product Manager Velma Noble</p> | <p>3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted</p> |
| <p>4. Company/Product (Name) Lonza Formulation DC-110N</p> | <p>PM# 31</p> | |
| <p>5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401</p> <p><input type="checkbox"/> Check if this is a new address</p> | | <p>6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name</p> |

Section - II

| | |
|--|--|
| <input checked="" type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Not Subject to PRIA

Label Amendment to update Storage and Disposal language per PR Notice 2007-4 and to add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1.

Section - III

| | | | | | |
|---|---|---|--|---|---|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| <p>Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted</p> | <p>Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container</p> | <p>Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container</p> | | | <p><input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)</p> |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container | | 4. Size(s) Retail Container 1 oz. to bulk | | 5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled | | | | | |

Section - IV

| | | |
|--|---|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) | | |
| Name Joanna Holcombe | Title Sr. Commercial Regulatory Services Associate | Telephone No. (Include Area Code) 201-336-9297 |
| <p align="center">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p> | | <p>6. Date Application Received _____ (Stamped)</p> |
| 2. Signature  | 3. Title Sr. Commercial Regulatory Services Associate | |
| 4. Typed Name Joanna Holcombe | 5. Date February 9, 2011 | |

LONZA FORMULATION DC-110N

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 / 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..... 3.85%
Inert Ingredients: 96.15%
Total: 100.00%

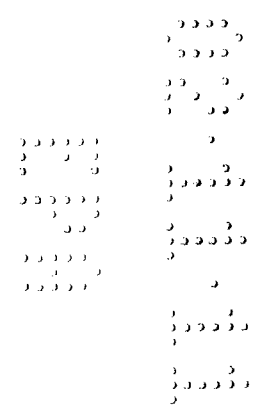
KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

See (side) (left) (right) (back) panel for Precautionary Statements and First Aid.

EPA Reg. No. 6836-204
EPA Est. No. (as noted on the container)
Net Contents (as noted on the container)
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

Manufactured by:
LONZA INC.
90 Boroline Road
Allendale, NJ 07401



Cross-contamination is of major housekeeping concern not only in hospitals, but also in schools, institutions and industry. **LONZA FORMULATION DC-110N** has been formulated to aid in the reduction of cross-contamination from treated surfaces in these areas.

LONZA FORMULATION DC-110N 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 DC-110N is an effective one-step sanitizer-cleaner for use on non-food, contact surfaces.

When used as directed, **LONZA FORMULATION DC-110N** 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 DC-110N 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 and exercise facilities.

Use **LONZA FORMULATION DC-110N** 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-110N is a no-rinse neutral pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

LONZA FORMULATION DC-110N can be used with a mop and bucket, trigger sprayers, sponge or by soaking.

LONZA FORMULATION DC-110N provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to re-coat.

LONZA FORMULATION DC-110N improves labor results by effectively controlling odors.

LONZA FORMULATION DC-110N 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 DC-110N** for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

Use **LONZA FORMULATION DC-110N** in kitchens, bathrooms and other household areas.

LONZA FORMULATION DC-110N kills household germs; effective against Pseudomonas aeruginosa (Pseudomonas), Staphylococcus aureus (Staph) and Streptococcus pyogenes (Strep), Influenza A/PR and Trichophyton mentagrophytes (Athlete's foot fungus).

LONZA FORMULATION DC-110N is a neutral pH multi-surface cleaner, deodorizer and disinfectant. Use on windows, mirrors and other glass surfaces.

Use **LONZA FORMULATION DC-110N** on the multi-touch surfaces responsible for cross-contamination.

Use **LONZA FORMULATION DC-110N** 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, outdoor furniture, desks, telephones, door knobs and handles, and glass surfaces including windows and mirrors.

LONZA FORMULATION DC-110N is recommended for Poultry Premise Sanitation (Hatcheries):

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

LONZA FORMULATION DC-110N is recommended for Swine Premise Sanitation:

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

LONZA FORMULATION DC-110N is a Hospital Disinfectant at 2 oz. per gallon (16 mL per liter, 1:64 dilution), modified in the presence of 250 ppm hard water, and at 3 oz. per gallon (24 mL per liter, 1:42 dilution), modified in the presence of 400 ppm hard water.

LONZA FORMULATION DC-110N 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 enterica | 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
- *Herpes Simplex Virus Type 1
- *Herpes Simplex Virus Type 2
- *HIV-1 (AIDS virus)
- *Influenza A/PR
- *Rubella
- *Vaccinia Virus

LONZA FORMULATION DC-110N is a sanitizer for hard, nonporous, non-food, contact surfaces at 2 - 3 oz. per gallon (16 - 24 mL per liter) against:

- Enterobacter aerogenes
- Staphylococcus aureus

(Note to reviewer: the following is considered optional marketing language:)

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus.

DIRECTIONS FOR USE:

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

(Note to 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 pre-clean 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 250 ppm, add 2 oz. per gallon (16 mL per liter) of water (1:64).

For water hardness up to 400 ppm, add 3 oz. per gallon (24 mL per liter) of water (1:42).

For heavy duty use, add 8 oz. per gallon (64 mL per liter) of water (1:16).

(Note to reviewer: The following Preparation of Use Solution is to be used with the closed spray bottle system and small cartridge containing concentrate [cartridge label and Preparation of use appears on pages 10 & 11 of this master label.] 0.37 fl. oz. per 24 oz. is equivalent to 2 oz per gallon)

For water hardness up to 250 ppm, add 0.37 fl. oz. (11 mL) of Lonza Formulation DC-110N in 24 fl. oz. of water.

DISINFECTION / VIRUCIDAL / FUNGICIDAL DIRECTIONS:

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

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. 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.

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. Do not use on 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 more often if 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 DC-110N.

Contact time:

For HIV-1: Use 2 oz. of Lonza Formulation DC-110N per gallon of water (16 mL per liter). Leave surfaces wet for 2 minutes.

For HBV: Use 3 oz. of Lonza Formulation DC-110N per gallon of water (24 mL per liter). Leave surfaces wet for 10 minutes.

For disinfection against all other bacteria and fungi claimed: Use a 10-minute contact time

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 2 - 3 oz. (60 - 90 mL) 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 2 - 3 oz. per gallon (16 - 24 mL 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 8 oz. per gallon (64 mL 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 - 4 oz. per gallon of water (8 - 32 mL per liter) 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 2 - 3 oz. per gallon of water (16 - 24 mL per liter), to sanitize hard, nonporous, environmental surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.

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 2 - 3 oz. of **LONZA FORMULATION DC-110N** per gallon of water. Apply use-solution with a cloth, mop or pressure sprayer so as to thoroughly wet surfaces. Wipe dry with a clean cloth or sponge 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 2 - 3 oz. of **LONZA FORMULATION DC-110N** per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. 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. 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.

HATCHERIES: Use 2 - 3 oz. of **LONZA FORMULATION DC-110N** per gallon of water to treat hatcheries, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

VEHICLES: Clean all vehicles including mats, crates, cabs and wheels with high pressure water, and **LONZA FORMULATION DC-110N**. Use 2 - 3 oz. per gallon to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

SHOE BATH SANITIZER DIRECTIONS: 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 2 - 3 oz. per gallon of water solution for 60 seconds prior to entering the area. Change the solution in the bath daily or more often if the solution appears diluted or soiled.

DRESSING PLANT DISINFECTANT 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 the recommended use solution of 2 oz. per gallon. 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 four parts **LONZA FORMULATION DC-110N** to five parts water (2 gallons of **LONZA FORMULATION DC-110N** 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. When fogging is completed, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried.

SANITIZING INCUBATORS AND HATCHERS USING FOGGING DEVICES

Mix 24 oz. **LONZA FORMULATION DC-110N** to 122 oz. 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 breathe 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 2 - 3 oz. per gallon solution of **LONZA FORMULATION DC-110N** 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.

