

6836-71

11/18/2009

1 of 8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

NOV 18 2009

SUBJECT: Lonza Formulation Y-59  
EPA Registration Number: 6836-71  
Application Date: August 17, 2009  
Receipt Date: August 21, 2009

Dear Ms. Joanna Holcombe:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

1) Delete the word "Tolerance" from page one. A tolerance is a term associated with a pesticide product which may be applied to food. This term is not appropriate for your product as there are no food applications.

2) Revise the Precautionary Statements to be in agreement with the Label Review Manual as follows: "...Wash thoroughly with soap...before eating, drinking, *using tobacco or using the toilet.* Remove contaminated..."

3) Add the following to the Environmental Hazards statement such that this section will reflect the environmental concerns associated with these active ingredients: "This pesticide is toxic to fish *and aquatic invertebrates.* Do not discharge..."

4) Revise the first set of optional marketing statements on page two to include the following language: "...aid in the reduction of cross contamination *on treated surfaces* in institutions, schools and hospitals."

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5) This product is not for use on food contact surfaces including interior surfaces of appliances, and all surfaces of utensils, glassware and dishes. As such, make the following clarifications to your label. Revise the first statement in the Cleaning and Disinfections Directions on page three to include: "...chairs, countertops, *exterior surfaces of appliances*, sinks, toilet bowls..." In addition, revise the following statement by deleting the "as a disinfectant" phrase: "Do not use on utensils, glassware and dishes."

3) Revise the Storage and Disposal directions as follows. Delete the first set of Storage and Disposal statements on page five and replace with the following language.

**“(Note to reviewer: For Containers five gallons or less for refillable containers that do not meet the container rule definition of refillable. The nonrefillable container statement will be removed when directions for how the pesticide user refills the container are included:)”**

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children.

(Nonrefillable container.) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for recycling if available.

(or)

(Nonrefillable container.) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for reconditioning if appropriate.”

a) Revise the second Storage and Disposal section by revising the note to reviewer to read as follows:

**“(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products)”**

b) Revise the Container Disposal statement in the second section to read as follows:

**“CONTAINER DISPOSAL:**

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

**(Plastic and Metal Containers:)** Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple

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rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For metal containers only: DO NOT cut or weld metal containers.)

(For Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities."

**General Comments**

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

7510P:T.Lantz:11/16/09:6836-71a accepted label amend  
Enclosure: Stamped accepted label

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# LONZA FORMULATION Y-59

Heavy Duty  
Disinfectant-Cleaner-Fungicide  
Mildewstat-Virucide\*-Sanitizer-Deodorizer  
with Organic Soil Tolerance  
Plus Disinfectant Hard Water  
(400 ppm Calculated as CaCO<sub>3</sub>) ~~Tolerance~~  
for Non-Medical Areas\*\*  
Hospital-Institutional-Industrial and School Uses

Active Ingredients:

Alkyl (C<sub>14</sub>, 50%; C<sub>12</sub>, 40%; C<sub>16</sub>, 10%)  
dimethyl benzyl ammonium chloride..... 1.024%  
Octyl decyl dimethyl ammonium chloride. 0.768%  
Dioctyl dimethyl ammonium chloride ..... 0.307%  
Didecyl dimethyl ammonium chloride ..... 0.461%  
Other Ingredients ..... 97.440%  
TOTAL ..... 100.000%

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

**NOV 17 8 2009**

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

KEEP OUT OF REACH OF CHILDREN

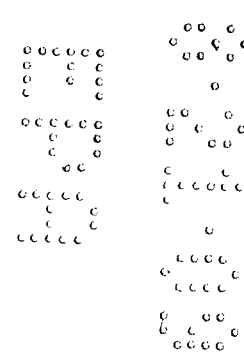
6836-71

## DANGER

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

EPA Reg. No. 6836-71 •  
EPA Est. No. (insert EPA Est. No. here)  
Net Contents (insert container size here)  
[Country of origin (insert country)]  
[Manufactured in (insert country)]  
[Barcode]

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



5098

**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 or face shield), protective clothing and protective gloves (rubber or chemical resistant). Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

**FIRST AID**

**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.

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

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

*(Use this statement if container is 5 gallons or greater)*

**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.

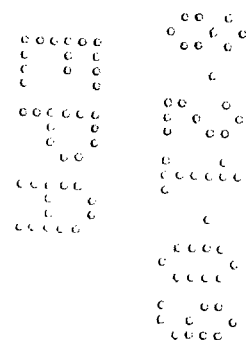
*(Note to reviewer: The following is considered optional marketing language.)*

**LONZA FORMULATION Y-59** is a heavy-duty disinfectant cleaner with cleaning efficiency. It has been formulated to aid in the reduction of cross-contamination in institutions, schools and hospitals.

**LONZA FORMULATION Y-59** is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal, fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

**LONZA FORMULATION Y-59** is an effective one-step sanitizer-cleaner for use on porous and non-porous non-food contact surfaces in waters up to 400 ppm hardness.

**LONZA FORMULATION Y-59** is a proven "one-step" cleaner – disinfectant – sanitizer – fungicide – mildewstat - virucide in the presence of organic soil and up to 400 ppm hard water.\*\*



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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.

**CLEANING AND DISINFECTION DIRECTIONS:**

Apply **LONZA FORMULATION Y-59** to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, sinks, toilet bowls, urinals and bedframes with a cloth, mop or coarse mechanical spray device so as to thoroughly wet surfaces. . Treated surfaces must remain wet for ten minutes. Wipe dry with a clean cloth or sponge or allow to air dry.

For heavily soiled areas, a preliminary cleaning is required.

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 ~~as a disinfectant.~~

Prepare a fresh solution daily or more often if use solution becomes visibly dirty or soiled.

*(Note to reviewer: Only One of the following two statements will 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.

**NON-MEDICAL USE AREAS –**

**For Schools, Public Rest Rooms, Athletic Facilities, Transportation Terminals, Hotels, Motels and Other Non-Medical Institutional and Industrial Uses:**

At 2 oz. per gallon use level, the activity of **LONZA FORMULATION Y-59** has been evaluated in the presence of 5% serum by the AOAC Use-Dilution method and found to be effective against a broad spectrum of gram positive and gram negative organisms as represented by:

- Brevibacterium ammoniagenes
- Escherichia coli
- Enterobacter aerogenes
- Klebsiella pneumoniae
- Proteus mirabilis
- Salmonella enterica
- Salmonella schottmuelleri
- Salmonella typhi
- Serratia marcescens
- Shigella dysenteriae
- Staphylococcus aureus
- Streptococcus pyogenes

**\*\*NON-MEDICAL USE AREAS:**

At 3 oz. per gallon use level prepared in water up to 400 ppm hardness, the activity has been evaluated in the presence of both 5% blood serum and 400 ppm hard water against the above referenced organisms. Follow disinfection directions.

**FOR HOSPITALS, MEDICAL AND DENTAL OFFICES, NURSING HOMES AND OTHER HEALTH CARE FACILITIES:** At 3 oz. per gallon use level, **LONZA FORMULATION Y-59** is effective against *Pseudomonas aeruginosa*, as well as the broad spectrum of organisms listed in the non-medical areas. The same AOAC test used above were used to confirm suitable performance. Follow disinfection directions.

708

**MILDEWSTATIC PERFORMANCE:** At 2 oz./gallon, **LONZA FORMULATION Y-59** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces (as indicated in general instructions above). Follow disinfection directions. Allow to dry on surface and repeat weekly or more often if mildew growth returns.

**VIRUCIDAL PERFORMANCE\*:** At 2 oz. per gallon use-level, **LONZA FORMULATION Y-59** was evaluated in the presence of 5% serum and found to be effective against the following viruses: Influenza A (Brazil) virus, Herpes Simplex Type 1, Vaccinia and Avian Influenza on inanimate environmental surfaces. Follow disinfection directions.

**FUNGICIDAL PERFORMANCE: -**

**LONZA FORMULATION Y-59** is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used at 2 oz. per gallon in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, etc. Follow disinfection directions.

**NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER APPLICATION:**

Remove gross filth prior to disinfection.

**From concentrate:**

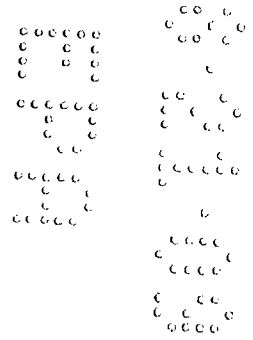
Add 1.5 oz. to the bowl (0.75 gallons) and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

**From Use-Dilution:**

Empty toilet bowl or urinal and apply a 2 oz./gal. use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or coarse mechanical spray. Brush or swab thoroughly, allow to stand for 10 minutes and flush.

**SANITIZING NON-FOOD CONTACT SURFACES: (such as floors, walls, tables)**

At ¼ oz./gallon use-level (150 ppm active quat), **LONZA FORMULATION Y-59** is an effective sanitizer in waters of up to 400 ppm hardness against Staphylococcus aureus and Klebsiella pneumoniae for both hard porous and nonporous surfaces. Treated surfaces must remain wet for at least 30 seconds. Wipe dry with a clean cloth, mop or sponge or allow to air dry.



8098

~~(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household or Residential)~~

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple-rinse as follows: Fill container 1/2 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple-rinse as follows: Fill container 1/2 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate.

~~(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less)~~

**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 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:**~~

~~Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. (Plastic Containers.) Triple-rinse as follows: Fill container 1/2 full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple-rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.~~

~~(Metal Containers.) Triple-rinse as follows: Fill container 1/2 full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple-rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. DO NOT heat or weld metal containers.~~

