

6836-28

11-19-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

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

NOV 19 2009

**Subject:** Lonza Disinfectant Cleaner 19-a.  
**Registration No.:** 6836-028  
**Amendment Dated:** August 19, 2009  
**Submission #:** 857031

Dear Ms. Holcombe,

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

**Proposed Amendment**

- Add optional barcode, "country of origin" statement and "manufactured in" statement;
- Update the company address;
- Revise *Salmonella choleraesuis* to its new name *Salmonella enterica*;
- Update the Storage and Disposal language per PR Notice 2007-4

**Conditions**

Revise the label as follows:

1) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Delete the "Storage and Disposal" Instructions for containers one gallon or less w/ uses other than household/residential. Also revise the second "Note to reviewer" to read "*Containers institutional/industrial/commercial uses.*"

2) The Container Rule established rinsate instructions for commercial, institutional, and industrial containers sold in containers five gallons or less and containers greater than five gallons. Therefore, revise the "Container Disposal" statements as follows:

**CONCURRENCES**

SYMBOL								
SURNAME								
DATE								

a) Your proposed "Container Disposal" statements are acceptable for containers five gallons or less. You need to add the following descriptor above the statement, "*(Containers 5 gallons or less).*"

b) If you sell your product in containers greater than 5 gallons, you must add the following statements:

*(Container greater than 5 gallons)*

Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.


- Page 2)** - Remove the first aid statement from page two and place it on page one.
- Under the "Environmental Hazard" section please include the statement, "This product is toxic to fish and other aquatic organisms".

**General Comments:**

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Velma Noble PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,



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

Enclosure: Stamped Label

# LONZA DISINFECTANT CLEANER (19-a)

Disinfectant-Cleaner-Sanitizer-Fungicide  
Mildewstat-Virucide\*-Deodorizer  
with Organic Soil Tolerance for  
Hospital, Institutional and Industrial Use

Active Ingredient:  
Didecyl dimethyl ammonium chloride ..... 4.5%  
Other Ingredients ..... 95.5%  
Total: ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

## DANGER

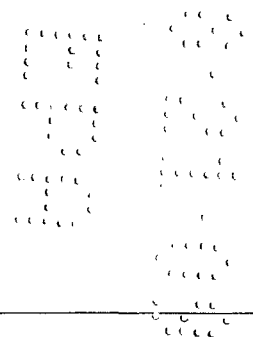
See (left) (right) (back) (side) panel for Precautionary Statements and First Aid.

EPA Registration No. 6836-28  
EPA Est. No. *(insert EPA Establishment number 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

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

**NOV 19 2009**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. **6836-28**



**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, safety glasses or face shield), protective clothing and protective gloves (rubber or chemical resistant). Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing 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.

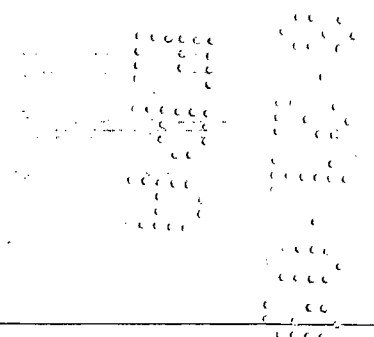
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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

*(Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statements will be used.)*

**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.



Cross contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. **LONZA DISINFECTANT-CLEANER 19-a** is formulated for this problem area. It both cleans and disinfects effectively and is virucidal when used as directed. Its hard nonporous surface disinfecting action will reduce the hazard of cross-contamination.

**LONZA DISINFECTANT-CLEANER 19-a** is an effective one-step sanitizer for non-food contact surfaces. It cleans and sanitizes in waters up to 850 ppm hardness. This hard water tolerance is in excess of most potable waters and will insure complete sanitizing action when used as directed.

Two ounces of **LONZA DISINFECTANT-CLEANER 19-a** per gallon of water will deodorize surfaces in bathrooms, garbage storage areas, and other areas where bacterial growth can cause malodors.

This product will inhibit the growth of mold and mildew and their odors.

**LONZA DISINFECTANT CLEANER 19-a** is a proven "one-step" cleaner – disinfectant – sanitizer – fungicide – virucide - mildewstat in the presence of moderate amounts of organic soil.

At 2½ oz. per gallon of water, the broad spectrum activity of **LONZA DISINFECTANT CLEANER 19-a** has been evaluated in the presence of 5% serum and found to be effective against the following organisms by the AOAC Use-Dilution test. The same AOAC tests confirm suitable performance for hospitals.

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella enterica
- Escherichia coli
- Streptococcus pyogenes
- Proteus mirabilis
- Klebsiella pneumoniae
- Enterobacter aerogenes
- Streptococcus faecalis
- Shigella dysenteriae
- Brevibacterium ammoniagenes

**AOAC Fungicidal Test**

At 2½ oz. per gallon, **LONZA DISINFECTANT CLEANER 19-a** 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, etc. Follow Hospital disinfection directions.

**Virucidal Performance\***

At 2 oz. per gallon use-level, **LONZA DISINFECTANT CLEANER 19-a** was evaluated in the presence of 10% serum and found to be effective against the following viruses:

- Adenovirus Type 5 (a causative virus in respiratory diseases)
- Herpes Simplex Type 1 (a member of the virus family that causes infectious mononucleosis)
- Vaccinia (representative of the pox viruses)
- Influenza A<sub>2</sub> (as represented by the strains commonly called the Hong Kong Flu and the London Flu Virus)

At 1¼ oz. per gallon, **LONZA DISINFECTANT CLEANER 19-a** will disinfect hard nonporous surfaces in schools, industry and non-medical institutions.

At 1¼ oz. per gallon of water, **LONZA DISINFECTANT CLEANER 19-a** delivers excellent cleaning and germicidal effectiveness. It is effective against Escherichia coli.

- Salmonella enterica
- Staphylococcus aureus

**DIRECTIONS FOR USE**

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

**For Disinfection in hospitals, nursing homes, and other medical institutions:** Use 2½ oz. per gallon of water. At this use-level, **LONZA DISINFECTANT CLEANER 19-a** is also virucidal and fungicidal.

**For Disinfection in schools, offices, and non-medical, commercial and industrial areas:** Use 1¼ oz. per gallon of water,

Apply **LONZA DISINFECTANT CLEANER 19-a** to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, sinks and bed frames with a cloth, mop or coarse (mechanical) spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry.

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.

For heavily soiled areas, a preliminary cleaning is required.

Prepare a fresh solution daily or when use solution becomes visibly dirty.

*(Note to reviewer: For products used on medical devices, 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. (Optional sentence: This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

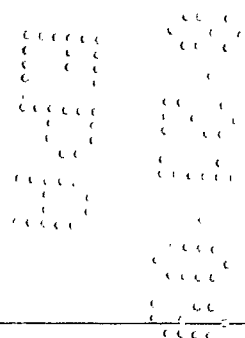
or

This product is not for use on medical device surfaces.

**Mold and Mildew Control:** At 1¼ oz. per gallon, **LONZA DISINFECTANT CLEANER 19-a** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow Disinfection Directions. Allow to dry on surface and repeat weekly (every 7 days) or more often if mildew growth returns.

**Sanitizing-Non-Food Contact Surfaces  
(such as floor, walls, tables, etc.)**

At 1 oz. per 2¼ gallon use-level, **LONZA DISINFECTANT CLEANER 19-a** is an effective sanitizer in waters up to 850 ppm hardness against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum on hard porous and non-porous non-food contact environmental surfaces. Apply use solution with a cloth, mop or coarse (mechanical) spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for 30 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.



***(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household and 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 ¼ 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 ¼ 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 over one gallon)***

**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 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 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 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 rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. **DO NOT** cut or weld metal containers.

