

EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 6836-28	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Disinfectant Cleaner 19-a	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401 <input type="checkbox"/> Check if this is a new address	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	

Section - II

<input 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 checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

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

Notification of label change to add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1

Not Subject to PRIA

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Signature: Joanna Holcombe Date: 3-10-2010

Section - III

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

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) 201-316-3297
Certification 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.		6. Date Application Received (Stamped)
2. Signature <u>Joanna Holcombe</u>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date March 10, 2010	

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Lonza

Via FedEx

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIFY)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Lonza Inc
Allendale
90 Boroline Road
Allendale, NJ 07401, USA

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

Tel 201-316-9297
Fax 201 696-3470
joanna.holcombe@lonza.com

March 10, 2010

**SUBJECT: Lonza Disinfectant Cleaner 19-a, EPA Registration No. 6836-28
Application for Label Notification**

Dear Ms. Noble:

The purpose of this notification is to add the following:

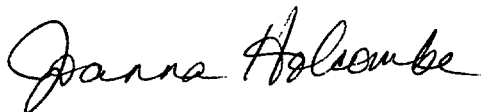
**Add optional marketing language per EPA Guidance for Testing and Labeling Claims
against Pandemic 2009 H1N1.**

Please find enclosed the following documents in support of this label notification.

- Application for Pesticide Notification
- One copy of the label with changes highlighted

Please provide your decision electronically to me at joanna.holcombe@lonza.com and subsequently send me a letter confirming the Agency's decision. If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely,
Lonza Inc.



Joanna Holcombe
Sr. Commercial Regulatory Services Associate

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

**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

This product is toxic to fish and other aquatic organisms. 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 A₂ (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

- 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.

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 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.

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, institutional/industrial/commercial uses)

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 is five gallons or less)

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.

(Container is over five gallons)

Container Disposal:

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. 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 sanitary landfill. 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.