

pm 31

6836-152

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Please read instructions on reverse before completing form. Form Approved OMB No. 2070-0060. Approval expires 05-31-98.



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
☒ Other

OPP Identifier Number
254005

Application for Pesticide - Section I

1. Company/Product Number 6836-152	2. EPA Product Manager Marion Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulation DC-103	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 17-17 Route 208 Fair Lawn, NJ 07410 <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 checked="" type="checkbox"/> Other - Explain below.

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

Notification updating Storage & Disposal statements, per PR Notice 83-3. This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the CSF of the 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 (cont

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Notification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. 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 Eliot I. Harrison	Title Agent for Lonza	Telephone No. (Include Area Code) (301) 652-5495	
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 	3. Title Agent for Lonza		
4. Typed Name Eliot I. Harrison	5. Date November 14, 1995		

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95-2 and 40 CFR 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. LONZA FORMULATION DC-103 has been formulated to aid in the reduction of cross-contamination in these areas.

LONZA FORMULATION DC-103 is a one-step disinfectant-cleaner that is effective against a broad spectrum of bacteria, is virucidal, fungicidal, and controls the growth of mold and mildew and their odors when used as directed.

When used as directed, LONZA FORMULATION DC-103 will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND
DOMESTIC ANIMALS**

Caution. Causes eye irritation. Avoid contact eyes or clothing. Wash thoroughly with soap and water after handling.

STORAGE AND DISPOSAL

- Do not contaminate water, food, or feed by storage or disposal.
- Do not store on side.
- Avoid creasing or impacting of side walls.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. 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

Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Metal Container: Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(If container is 1 gallon or less, use this container disposal statement.)

Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

"BEFORE LABEL"

LONZA FORMULATION DC-103

Disinfectant-Cleaner-Fungicide-
Mildewstat-Virucide*-Deodorizer
for Hospitals, Institutional and Industrial Use

Effective in the presence of 5% serum contamination

Active Ingredients

Octyl decyl dimethyl ammonium chloride	0.025%
Dioctyl dimethyl ammonium chloride	0.010%
Didecyl dimethyl ammonium chloride	0.015%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	0.034%

Inert Ingredients

99.916%
100.000%

CAUTION

**KEEP OUT OF REACH OF CHILDREN
STATEMENT OF PRACTICAL TREATMENT**

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Remove and wash contaminated clothing before reuse.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

<u>EPA Registration No.</u>	6836-152
<u>EPA Establishment No.</u>	6836-L-1
<u>Net Contents</u>	

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

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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.

LONZA FORMULATION DC-103 is a "onestep" disinfectant-cleaner-fungicide-mildewstat-virucide which is effective in the presence of 5% serum contamination.

Apply LONZA FORMULATION DC-103 undiluted to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks, tile, toilets, glazed porcelain, and bedframes with a cloth, mop, pump or mechanical spray device so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. For spray applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breath spray mist.

This product is not 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.

DISINFECTION - To disinfect hard, non-porous surfaces, treated surfaces must remain wet for 10 minutes.

For Schools, Industry and Medical Institutional Use:

The activity of LONZA FORMULATION DC-103 has been evaluated in the presence of 5% serum by the AOAC Use-Dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms tested:

<i>Pseudomonas aeruginosa</i>	<i>Enterobacter aerogenes</i>
<i>Staphylococcus aureus</i>	<i>Streptococcus faecalis</i>
<i>Salmonella choleraesuis</i>	<i>Shigella dysenteriae</i>
<i>Escherichia coli</i>	<i>Brevibacterium ammoniagenes</i>
<i>Streptococcus pyogenes</i>	<i>Salmonella typhi</i>
<i>Klebsiella pneumoniae</i>	<i>Serratia marcescens</i>

Non-Acid Toilet Bowl Disinfectant/Cleaner Application:

1. Empty toilet or urinal and apply to exposed surfaces with a cloth, mop, sponge, or mechanical spray.
2. Brush thoroughly over exposed surfaces including under the rim, allow to stand for 10 minutes, and flush.

MOLD AND MILDEW CONTROL. LONZA FORMULATION DC-103 will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

***VIRUCIDAL PERFORMANCE.** LONZA FORMULATION DC-103 was evaluated and found to be effective in the presence of 5% serum against the following viruses:

HIV-1 (AIDS virus)
Influenza A/Brazil
Herpes Simplex Type 1 and Type 2
Vaccinia

on inanimate hard non-porous environmental surfaces.

KILLS HIV-1 ON PRE-CLEANED 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 DC-103.

CONTACT TIME: Leave surface wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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FUNGICIDAL CONTROL. LONZA FORMULATION DC-103 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.

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