

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
248934

Application for Pesticide - Section I

1. Company/Product Number 6836-139	2. EPA Product Manager Marion Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulation R-82F	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 type="checkbox"/> Other - Explain below.

NOTIFICATION
APR 18 1996

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

Notification per PR Notice 95-2. This notification corrects a typographical error that was made in an amended label submitted to comply with PR Notice 94-4. Notification certification statement is attached.

Section - III

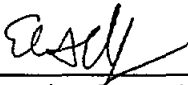
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/>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

Section - IV

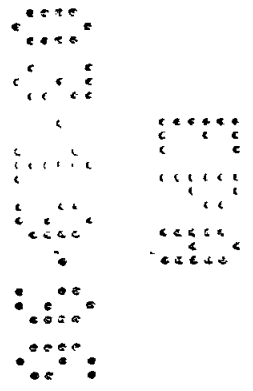
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Eliot I. Harrison	Title Agent for Lonza	Telephone No. (Include Area Code) (301) 652-5495
Certification I certify that the statements I have made on this 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 3/14/96	

CERTIFICATION STATEMENT

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 C.F.R. §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 if this notification is not consistent with the terms of PR Notice 95-2 and 40 C.F.R. §152.46 this product may be in violation of FIFRA and I may be subject to enforcement actions and penalties under sections 12 and 14 of FIFRA.



Eliot I. Harrison, Agent for Lonza



Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. LONZA FORMULATION R-82F has been formulated to aid in the reduction of cross-contamination in these areas.

LONZA FORMULATION R-82F is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, viruses (including HIV), fungi and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION R-82F is an effective one-step sanitizer-cleaner for use on food contact, as well as non-food contact surfaces. When used as directed, LONZA FORMULATION R-82F 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**

DANGER

Keep out of reach of children. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed or absorbed through skin. Avoid contamination of food.

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.

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 acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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.

Corrected copy

3 7 4

LONZA FORMULATION R-82F

DISINFECTANT, CLEANER, SANITIZER, FUNGICIDE
MILDEWSTAT, VIRUCIDE, DEODORIZER
FOR HOSPITALS, INSTITUTIONAL AND INDUSTRIAL USE

Active Ingredients

Octyl decyl dimethyl ammonium chloride	6.510%
Dioctyl dimethyl ammonium chloride	2.604%
Didecyl dimethyl ammonium chloride	3.906%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	8.680%

Inert Ingredients

78.300%
100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

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

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

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

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. 6836-139

EPA Establishment No. 6836-IL-1

Net Contents

MANUFACTURED BY:

LONZA INC., 17-17 Route 208, Fair Lawn, N.J. 07410

DIRECTIONS FOR USE

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

LONZA FORMULATION R-82F is a proven "one-step" disinfectant-cleaner-disinfectant-fungicide-mildewstat-virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination. Apply **LONZA FORMULATION R-82F** to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain and bedframes with a cloth, mop or mechanical spray device so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use solution becomes visibly dirty. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray mist.

DISINFECTION: To disinfect hard, non-porous surfaces, add 1/2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. The activity of **LONZA FORMULATION R-82F** has been evaluated in the presence of 5% serum and 400 ppm hard water by the AOAC Use-Dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by:

<i>Pseudomonas aeruginosa</i>	<i>Salmonella schottmuelleri</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>
<i>Enterobacter aerogenes</i>	<i>Pseudomonas cepacia</i>

VIRUCIDAL PERFORMANCE: At 1/2 oz. per gallon use level, **LONZA FORMULATION R-82F** was evaluated in the presence of 5% serum and 400 ppm hard water against the following viruses found on inanimate, hard, non-porous, environmental surfaces:

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

FUNGICIDAL CONTROL: **LONZA FORMULATION R-82F** 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 at 1/2 oz. per gallon.

MOLD AND MILDEW CONTROL. At 1/2 oz. per gallon, **LONZA FORMULATION R-82F** 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.

SANITIZING FOOD CONTACT SURFACES: At 1/2 oz. per 5 1/2 gallons water use **LONZA FORMULATION R-82F** for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plant and farms. Do not rinse with water. For heavily soiled equipment or utensils, pre-wash with **LONZA FORMULATION R-82F**. Rinse with clean water, then apply recommended dilution of **LONZA FORMULATION R-82F** with a cloth, mechanical spray device (spray surface until thoroughly wetted) or immersion. Treated surfaces must remain wet for one minute. Prepare a fresh solution for every use. DO NOT reuse mechanically applied use solution for sanitizing. **LONZA FORMULATION R-82F** can be used in accordance with the U.S. Public Health Service food service sanitation recommendation.

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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.

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other setting 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-1 must be thoroughly cleaned from surfaces and objects before application of **LONZA FORMULATION R-82F**.

CONTACT TIME: Leave surface wet for 10 minutes with 1/2 oz. per gallon use solution.

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.

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in a hot detergent solution.
2. Rinse utensils and equipment thoroughly with clean water.
3. Sanitize equipment and utensils by immersion in a 1/2 oz. per 5 1/2 gallon solution of **LONZA FORMULATION R-82F** (150 ppm active) for at least 60 seconds at a temperature of 75°F.
4. For equipment and utensils too large to sanitize by immersion, apply a 1/2 oz. per 5 1/2 gallon solution of **LONZA FORMULATION R-82F** (150 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
5. Allow sanitized surface to drain and air dry. Do not rinse.

Wash thoroughly with soap and water after handling.

