

6836-137

01107/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JAN -7 2010

Joanna Holcombe
Sr. Commercial Regulatory Services Associate
H & S Chemicals Division c/o Lonza Inc
90 Boroline Road
Allendale, NJ 07401

Subject: Lonza Formulation ~~70-12F~~ S-37F
EPA Registration No. 6836-137
Notification Date: December 11, 2010
EPA Receipt Date: December 14, 2010

Dear Ms. Holcombe,

This letter acknowledges receipt of your notification, submitted under the provisions of PR Notice 98-10 and FIFRA section 3(c)9.

Proposed Notification

- Update "Storage and Disposal" statement per PR Notice 2007-4
- Adding 2009 H1N1 marketing claims

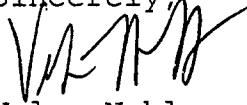
Based on a review of the material submitted, your notification to update the "Storage and Disposal" statement per PR Notice 2007-4 and add 2009 H1N1 marketing claims is acceptable. A copy has been inserted in our records for future reference.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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

1. Company/Product Number 6836-137	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulation S-37F	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 checked="" 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 type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

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

Amendment to update Storage and Disposal per PR Notice 2007-4 and to add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1

***Not Subject to PRIA* Please see Cover Letter for details.**

This notification is consistent with the provisions of PR Notice 98-10 and 2007-4 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, es

Date: 12-11-09

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	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Metal	
							<input type="checkbox"/> Plastic	
							<input type="checkbox"/> Glass	
							<input type="checkbox"/> Paper	
							<input type="checkbox"/> Other (Specify)	
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"/> Other _____				
				<input type="checkbox"/> Paper glued				
				<input type="checkbox"/> Stenciled				

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) 201-316-9297
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, es</u>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date December 11, 2009	



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

December 11, 2009

**SUBJECT: Lonza Formulation S-37F
EPA Registration No. 6836-137
Application for Label Amendment**

Notify

Dear Ms. Noble:

The Purpose of this amendment is to add the following:

**Update Storage and Disposal per PR Notice 2007-4.
Add optional marketing language per EPA Guidance for Testing and Labeling Claims
against Pandemic 2009 H1N1.**

**Please reference 6836-84 for previously approved Storage and Disposal wording for
Commercial, Industrial, Institutional product, no reuse rinsate statement.**

Please find enclosed the following documents in support of this label amendment:

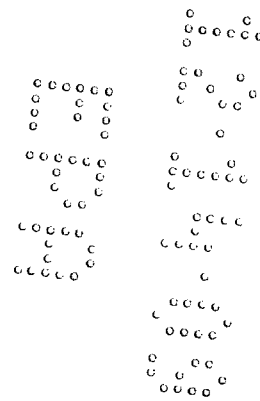
- Application for Pesticide Amendment
- One copy of the label with changes highlighted
- Two copies of the draft label

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
Joanna Holcombe

Sr. Commercial Regulatory Services Associate



LONZA FORMULATION S-37F

DISINFECTANT, CLEANER, SANITIZER, FUNGICIDE

MILDEWSTAT, VIRUCIDE, DEODORIZER

WITH ORGANIC SOIL TOLERANCE

FOR HOSPITALS, INSTITUTIONAL AND INDUSTRIAL USE

Active Ingredients

Octyl decyl dimethyl ammonium chloride.....	2.10%
Dioctyl dimethyl ammonium chloride	0.84%
Didecyl dimethyl ammonium chloride	1.26%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	2.80%
Other Ingredients	<u>93.00%</u>
Total:	100.00%

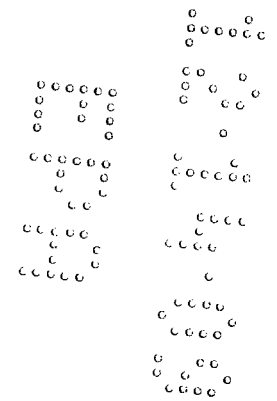
KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No.	6836-137
EPA Est. No.	<i>(Insert EPA Establishment No. Here)</i>
Net Contents	: <u><i>(insert container size here)</i></u>

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



PRECAUTIONARY STATEMENTS

HAZARD 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) when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. 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.

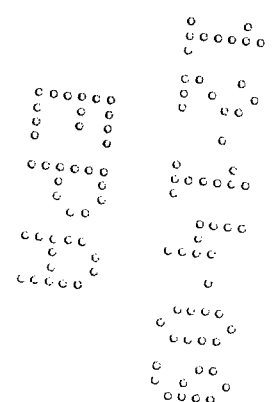
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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

(If the container size is 5 gallons or greater, 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 FORMULATION S-37F has been formulated to aid in reduction of cross-contamination in these areas.

LONZA FORMULATION S-37F 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 S-37F 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 S-37F 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.

DIRECTIONS FOR USE

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

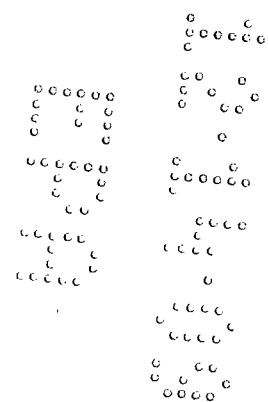
LONZA FORMULATION S-37F is a proven one-step cleaner – disinfectant – sanitizer – fungicide – mildewstat - virucide in the presence of moderate amounts of organic soil.

Apply LONZA FORMULATION S-37F to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, sinks, glazed tile, glazed porcelain 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 more often if the use solution becomes visibly dirty.

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.

DISINFECTION - To disinfect hard, nonporous surfaces, add 1 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. The activity of LONZA FORMULATION S-37F 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 positive organisms as represented by:

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella choleraesuis
- Brevibacterium ammoniagenes
- Escherichia coli
- Klebsiella pneumoniae
- Enterobacter aerogenes
- Proteus mirabilis
- Pseudomonas cepacia
- Salmonella schottmuelleri
- Serratia marcescens
- Shigella dysenteriae
- Streptococcus faecalis



VIRUCIDAL PERFORMANCE: At 1 oz. per gallon use-level LONZA FORMULATION S-37F was evaluated in the presence of 5% serum found to be effective against the following viruses found on hard, nonporous, surfaces:
Herpes Simplex Type 1 and Type 2
Influenza A/Brazil
Vaccinia

FUNGICIDAL PERFORMANCE:

LONZA FORMULATION S-37F 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 oz. per gallon. Follow disinfection directions.

MOLD AND MILDEW CONTROL: At 1 oz per gallon, LONZA FORMULATION S-37F 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.

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must 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)

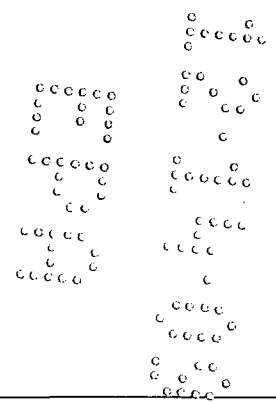
This product is not for use on medical device surfaces.

SANITIZING FOOD CONTACT SURFACES: At 1 oz. per 3½ gallons water use LONZA FORMULATION S-37F for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plants and farms. Prior to application, remove gross food particles and soil by a pre-flush or pre-scrape and when necessary, pre-soak to remove gross food particles and soil. Then thoroughly wash or flush equipment and utensils with a good detergent or compatible cleaner followed by a potable water rinse. Then, apply recommended dilution of LONZA FORMULATION S-37F with a cloth, mechanical spray device (spray surface until thoroughly wetted) or immersion. Treated surfaces must remain wet for one minute. Allow sanitized surfaces to drain or air dry. Do not rinse. Prepare a fresh solution for every use. DO NOT reuse mechanically applied use solution for sanitizing. LONZA FORMULATION S-37F can be used in accordance with the U.S. Public Health Service food service sanitation recommendation.

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

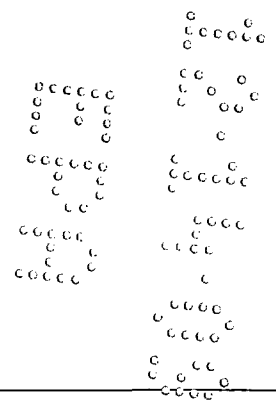
CLEANING AND SANITIZING: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

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 oz. Per 3 1/2 gallon solution of LONZA FORMULATION S-37F (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 oz. per 3 1/2 gallon solution of LONZA FORMULATION S-37F (150 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
5. Allow sanitized surface to drain and air dry. Do not rinse.



Note to reviewer: the following is considered optional marketing language:)

- 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.



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

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 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 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.

