

16836-141

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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
EPA Registration No. 6836-141
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.

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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 6836-141	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulation 70-12F	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, ER 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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<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, ER</u>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date December 11, 2009	

31

4/10



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 70-12F
EPA Registration No. 6836-141
Application for Label Amendment**

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.**

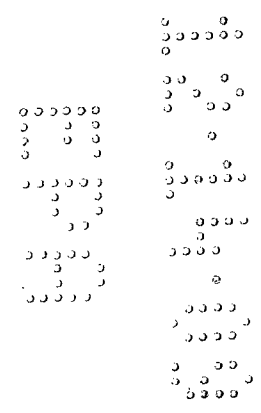
Please find enclosed the following documents in support of this label amendment:

- 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



5/10

LONZA FORMULATION 70-12F

HIGHLY CONCENTRATED GERMICIDE
BASED ON A UNIQUE BLEND OF QUATERNARIES
WITH ORGANIC SOIL LOAD TOLERANCE

DISINFECTANT, CLEANER, SANITIZER, FUNGICIDE
MILDEWSTAT, VIRUCIDE*, DEODORIZER
WITH ORGANIC SOIL TOLERANCE
FOR HOSPITALS, INSTITUTIONAL AND INDUSTRIAL USE

Active Ingredients

Octyl decyl dimethyl ammonium chloride.....	3.750%
Dioctyl dimethyl ammonium chloride	1.500%
Didecyl dimethyl ammonium chloride	2.250%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	5.000%
Other Ingredients	87.500%
TOTAL INGREDIENTS	100.000%

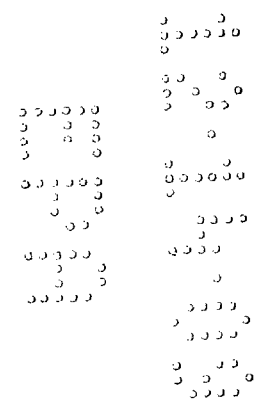
KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Registration No. 6836-141
EPA Establishment No. _____
Net Contents

Manufactured by:
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401



Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. **LONZA FORMULATION 70-12F** 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 from environmental surfaces.

LONZA FORMULATION 70-12F 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 70-12F** will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and will inhibit the growth of mold and mildew and their odors when used as directed.

DIRECTIONS FOR USE

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

LONZA FORMULATION 70-12F is a proven one-step cleaner-disinfectant-sanitizer-fungicide-mildewstat-virucide* in the presence of moderate amounts of organic soil.

Apply **LONZA FORMULATION 70-12F** 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.

DISINFECTION – To disinfect hard, non-porous surfaces, add 1/2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry or wipe excess liquid with a cloth, sponge or mop.

At this use-level, **LONZA FORMULATION 70-12F** is also virucidal and fungicidal.

Rinse all surfaces that come in contact with food such as countertops, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

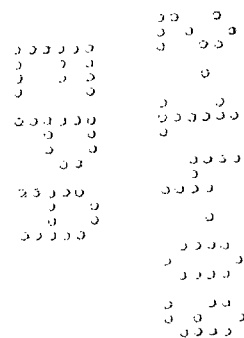
The broad spectrum activity of **LONZA FORMULATION 70-12F** has been evaluated at 1/2 oz. per gallon in the presence of 5% serum and found to be effective against the following by the AOAC Use-Dilution test:

- Pseudomonas aeruginosa
- Salmonella schottmuelleri
- Staphylococcus aureus
- Streptococcus faecalis
- Salmonella choleraesuis
- Shigella dysenteriae
- Escherichia coli (E. coli)
- Klebsiella pneumoniae
- Pseudomonas cepacia
- Enterobacter aerogenes
- Brevibacterium ammoniagenes

VIRUCIDAL PERFORMANCE*. At 1/2 oz. per gallon use-level, **LONZA FORMULATION 70-12F** was evaluated in the presence of 5% serum and found to be effective against the following viruses found on inanimate hard, non-porous environmental surfaces:

- Influenza A₂/Hong Kong
- Herpes Simplex Type 1 and Type 2
- Vaccinia

AOAC FUNGICIDAL TEST: **LONZA FORMULATION 70-12F** 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.



MILDEWSTATIC PERFORMANCE: At 1/2 oz. per gallon, **LONZA FORMULATION 70-12F** 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. Repeat (weekly) (every 7 days) or more often if mildew growth returns.

SANITIZING FOOD CONTACT SURFACES: At 1/3 oz. per 2 gallons water, use **LONZA FORMULATION 70-12F** for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plants and farms. Do not rinse with water. For heavily soiled equipment or utensils, pre-wash with **LONZA FORMULATION 70-12F**. Rinse with clean water, then apply recommended dilution of **LONZA FORMULATION 70-12F** 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 70-12F** can be used in accordance with the U.S. Public Health Service food service sanitation recommendation.

(Note to reviewer: 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.

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 1/3 oz. per 2 gallon solution of **LONZA FORMULATION 70-12F** (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 1/3 oz. per 2 gallon solution of **LONZA FORMULATION 70-12F** (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.

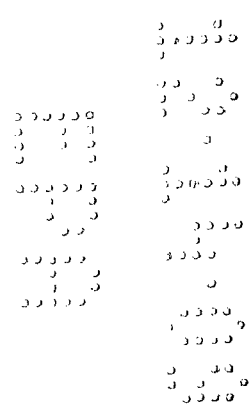
SANITIZING NON-FOOD CONTACT SURFACES:

(such as floors, walls, tables)

At 1/3 oz. per 2 gallons of water, **LONZA FORMULATION 70-12F** is an effective sanitizing agent against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and nonporous non-food contact environmental surfaces.

Apply use solution with a mop, cloth or coarse mechanical sprayer so as to thoroughly wet surfaces. Treated surfaces must remain wet for 30 seconds. Allow surfaces to air dry or wipe excess liquid with a cloth, sponge or mop.

(If container is one gallon or less, use this container disposal statement:)



9/10

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.

Handwritten marks consisting of small circles and lines, possibly representing a signature or initials, located in the bottom right corner of the page.

10/10

(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.

