

6836-141

6/22/2010

1096

JUN 22 2010

Joanna Holcombe
Sr. Commercial Regulatory Service Associate
Lonza inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Lonza Formulation 70-12F
EPA Registration No. 6836-141
Amendment Dated: March 22, 2010
EPA Received Date: March 24, 2010

Dear Joanna Holcombe

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable.

Proposed Amendment

- Revised Storage and Disposal Per PR Notice 2007-4
- Add marketing Language for H1N1 Virus

General Comments

A stamped copy of the accepted labels are enclosed for your records. Submit (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit revised labeling for review by the agency. Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble

* Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2086

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%
Diocetyl 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%

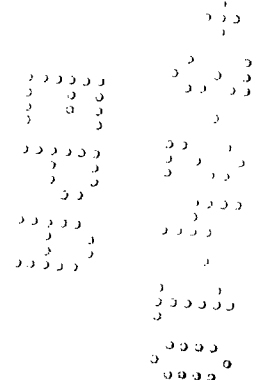
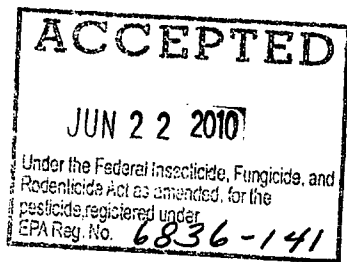
KEEP OUT OF REACH OF CHILDREN

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



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**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) when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

FIRST AID

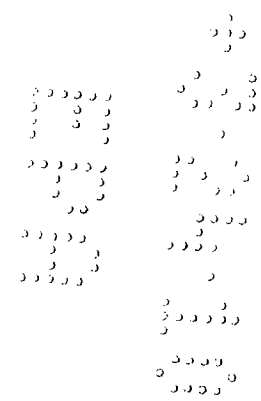
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

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.
(If container size is 1 gallon or less, the following storage and disposal statements will be used:)



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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 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.

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.

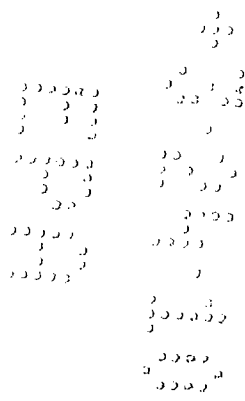
SANITIZING NON-FOOD CONTACT SURFACES:

(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:)



leaf

Note to reviewer: The following is considered optional marking 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 1/4 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.

