

6836-137

6/22/2010

1 of 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 22 2010

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

Subject: Lonza Formulation S-37F
EPA Registration No. 6836-137
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
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2096

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%

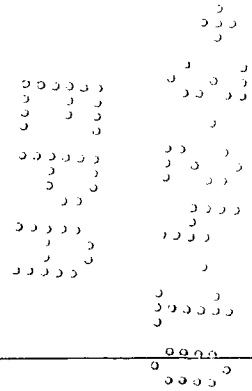
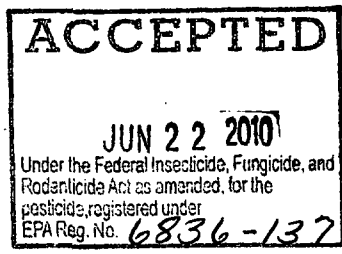
KEEP OUT OF REACH OF CHILDREN

DANGER

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

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

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



3096

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.

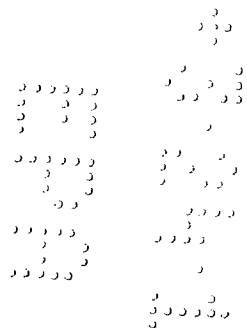
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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.

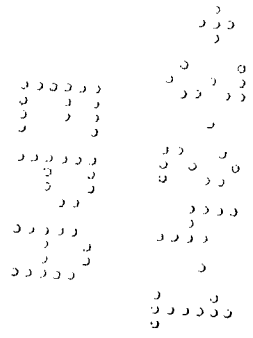
LONZA FORMULATION S-37F is a proven one-step cleaner – disinfectant – sanitizer – fungicide – mildewstat - virucide in the presence of moderate amounts of organic soil.

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:)

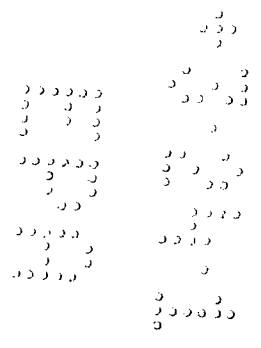
This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does 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 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.

