

6836-22

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



Office of Pesticide Programs

Joanna Holcombe,
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401, USA

MAR 31 2010

Attention Mrs. Joanna Holcombe.

Subject: Lonza Disinfectant Cleaner 30-3
Registration No.: 6836-22
Amendment Dated: December 30, 2009
Receipt Date: December 31, 2009
Submission #: 865847

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

Proposed Amendment

- Revise the Precautionary Statement and First Aid location;
- Add optional barcode, "country of origin" statement and "manufactured in" statement;
- Updated the company address;
- Revise nomenclature for Salmonella enterica and add "manufactured in statement";
- Update H1N1 labeling claim;
- Updated the Storage and Disposal language per PR Notice 2007-4.

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions or comments concerning this letter, please contact Velma Noble PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Velma Noble,
Product Manager, Team 31
Regulatory Management Branch

CONCURRENTLY Microbials Division (7510P)

SYMBOL	Enclosure							
SURNAME								
DATE								

**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), protective clothing and protective (rubber, chemical resistant) gloves. Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash 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.

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.

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

Cross contamination is of major housekeeping concern not only in hospitals, but in schools, colleges, universities, institutions and industry. **LONZA DISINFECTANT-CLEANER 30-3** 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. Also, this product will inhibit the growth of mold and mildew and their odors when used as directed.

LONZA DISINFECTANT CLEANER 30-3 is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-virucide-mildewstat in the presence of moderate amounts of organic soil.

Use **LONZA DISINFECTANT CLEANER 30-3** on walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, sinks and bedframes.

The broad spectrum activity of **LONZA DISINFECTANT CLEANER 30-3** has been evaluated at 2½ oz. per gallon in the presence of 5% serum and found to be effective against the following organisms by the *AOAC Use-Dilution test*.

Staphylococcus aureus
Pseudomonas aeruginosa
Salmonella enterica

Brevibacterium ammoniagenes
Enterobacter aerogenes
Escherichia coli E. coli
Klebsiella pneumoniae
Proteus mirabilis
Shigella dysenteriae
Streptococcus faecalis
Streptococcus pyogenes

Virucidal Performance*

*At 2 oz. per gallon use-level, **LONZA DISINFECTANT CLEANER 30-3** was evaluated in the presence of 10% serum and found to be effective against the following viruses:

Adenovirus Type 5 (a causative virus in respiratory diseases)
Herpes Simplex Virus Type 1 (a member of the virus family that causes infectious mononucleosis)
Vaccinia Virus (representative of the pox viruses)
Influenza Virus A₂ as represented by the strains commonly called the Hong Kong Flu Virus and the London Flu Virus

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.

LONZA DISINFECTANT CLEANER 30-3 is an effective sanitizer at ½ oz. per gallon use-level, in waters up to 1000 ppm hardness in the presence of 5% serum on hard porous and nonporous environmental surfaces against:

Klebsiella pneumoniae
Staphylococcus aureus

DIRECTIONS FOR USE

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

For heavily soiled areas, preclean first.

DISINFECTION / VIRUCIDAL DIRECTIONS: Add 2½ oz. per gallon of water. Apply with a cloth, mop or coarse (mechanical) spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry.

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

Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or dirty.

AOAC Fungicidal Test

At 2½ oz. per gallon, **LONZA DISINFECTANT CLEANER 30-3** 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. Follow Disinfection Directions.

Mold and Mildew Control: At 2½ oz. per gallon, **LONZA DISINFECTANT CLEANER 30-3** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow Disinfection Directions. Allow to dry on surface and repeat weekly or more often if mildew growth returns.

(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. 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-Non-Food Contact Surfaces (such as floor, walls, tables):

Sanitizing - To sanitize porous and nonporous non-food contact surfaces, apply 1/2 oz. **LONZA DISINFECTANT CLEANER 30-3** per gallon of water with a cloth, mop, sponge or mechanical sprayer. Thoroughly wet surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.

(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.