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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

May 27, 2003

Robert J. Sloan LONZA, Inc. 17-17 Route 208 Fair Lawn, NJ 07410

Subject:

Lonza Formulation 1-1.75

EPA Registration No. 6836-81 Application Date: March 7, 2003 Receipt Date: March 10, 2003

Dear Mr. Sloan:

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

- revisions to comply with PR Notice 2001-1
- minor label changes

Conditions

- 1. You must provide a Hotline Telephone number under the First Aid statement as per PR Notice 2001-1.
- 2. Revise the "Environmental Hazards" statement to start with the sentence "This product is toxic to fish and aquatic organisms."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit a copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES									
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DATE	5/2/1/3								

Should you have any questions or comments concerning this letter, please contact Wanda Mitchell at (703) 308-6345.

Sincerely,

Robert S. Brennis

Product Manager - Team 32

Regulatory Management Branch II

Antimicrobials Division (7510C)

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 goggles or face shield and protective gloves (rubber, chemical resistant) when handling. Harmful or fatal if swallowed. Do not breathe spray. Avoid contamination of food.

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 eve. 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. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(Note to reviewer: For containers that are 5 gallons or larger, 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.

LONZA **FORMULATION 1-1.75**

Disinfectant - Cleaner - Sanitizer - Deodorizer With Organic Soil and 400 ppm Hard Water Tolerance

> For Hospital, Institutional, Industrial, School, Dairy, and Other Farm Use

Active Ingredient:	
Alpha-(P-nonylphenyl)-Omega-hydroxypoly	
(oxyethylene)-lodine Complex	18.05%
(Providing 1.75% titratable iodine)	
Other Ingredients	<u>81.95%</u>
Total:	

KEEP OUT OF REACH OF CHILDREN **DANGER**

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

EPA Reg. No. 6836-81 EPA Est. No. (insert EPA Est. No. here) Net Contents (insert size of container here)

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

ACCEPTED with COMMENTS EPA Letter Dated:

MAY 2.7 2003

Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide. registered under EPA Reg. No. (p 836 - 81

Lonza Formulation I-1.75 EPA Reg. No. 6836-81 EPA Label amendment 3-06-03 (Note to reviewer: Language in () is optional or interchangeable)

LONZA FORMULATION I-1.75 is a proven "one-step" cleaner – disinfectant – sanitizer - deodorizer in the presence of moderate amounts of organic soil and 400 ppm hard water.

DIRECTIONS FOR USE

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

Apply LONZA FORMULATION I-1.75 with a cloth, mop, sponge or coarse mechanical spray device until surfaces are thoroughly wetted. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. Prepare fresh solution daily or more often if the use solution becomes visibly diluted or dirty.

Disinfection - Hospitals, Veterinary Clinics, Other Health Care Institutions, Institutions, Industry, Schools, Apply a use solution of ½ oz. of LONZA FORMULATION I-1.75 per gallon of water to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, countertop laminates, tile, glazed porcelain, and sinks. For heavily soiled areas, a preliminary cleaning is required.

Disinfection - Farm Premises and Poultry Houses:

Remove all animals and feed from premises, vehicles and enclosures such as coops and crates. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of ½ oz. of LONZA FORMULATION I-1.75 per gallon of water (or equivalent dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, boats and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries: Use ½ oz. of LONZA FORMULATION I-1.75 per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard nonporous surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

Shoe Bath Sanitizer - To prevent tracking harmful organisms into animal areas, scrape shoes and place in a 3 oz. of LONZA FORMULATION I-1.75 per gallon of water solution for 30 seconds prior to entering area.

(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 - Meat and food processing equipment and utensils: Remove heavy soils by flushing, scraping, or mopping. Wash with 1 oz. per gallon of LONZA FORMULATION I-1.75 (or other good cleaner). Rinse with clean water and sanitize surfaces with 1 oz. LONZA FORMULATION I-1.75 per 5 gallons of water (25 ppm titratable iodine). Surface should remain in contact with solution for 1 - 2 minutes. Drain well and air dry. Do not rinse.

Hand Sanitizing - In food handling and meat cutting operations: Rinse hands and immerse in a 1 oz. of LONZA FORMULATION I-1.75 per 5 gallons of water solution (25 ppm titratable iodine).

Retort Cooling Water - For canning operations. Add 1 oz. LONZA FORMULATION 1-1.75 per 5 - 10 gallons of retort water prior to starting up operation to control slime and odor causing bacteria.

Poultry Drinking Water Sanitization — Use 1 oz. of LONZA FORMULATION I-1.75 per 10 gallons of drinking water.

(Note to reviewer: If the container size is 1 gallon or less, the following Storage and Disposal Statements will be used:)

Storage and Disposal

Store in original container in areas inaccessible to children. Do not reuse empty container Discard in trash or recycle.

(Note to reviewer: If the container size is greater than 1 gallon, the following Storage and Disposal Statements will be used:)

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage:

Keep product under locked storage, inaccessible to children. Open dumping is prohibited. Do not reuse empty container. Do not store on side. Avoid creasing or impacting of side walls.

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, Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

(Plastic containers): Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

(Fiber drums with liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, dispose of liner in a sanitary landfill or by incineration, if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(Metal containers): Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Lonza Formulation I-1.75 EPA Reg. No. 6836-81 EPA Label amendment 3-06-03

(Note to reviewer: Language in () is optional or interchangeable)

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