

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

6836-81

11/8/2005

Page 136

November 8, 2005

Robert J. Sloan
 Sr. Regulatory Services Associate
 LONZA, Inc.
 90 Boroline Rd.
 Allendale, NJ 07401

Subject: Lonza Formulation I-1.75
 EPA Registration No. 6836-81
 Application Date: October 7, 2005
 Receipt Date: October 11, 2005

Dear Mr. Sloan:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- addition of alternate terminal sterilants disclaimer

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

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

Sincerely,

Wanda Y. Henson
 Product Reviewer (32)
 Regulatory Management Branch II
 Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL	7510C	7510C						
IRNAME	E. Belg	Henson						
DATE	11/8/05	11-8-05						

276

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number
302557

Application for Pesticide - Section I

1. Company/Product Number 6836-81	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulion I-1.75	PM# 32	
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 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 checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF ADDITION OF EQUIVALENT DILUTIONS
THIS SUBMISSION IS NOT SUBJECT TO FEES UNDER PRIA

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	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 <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
Certification must submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
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	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Robert J. Sloan	Title Sr. Regulatory Services Associate	Telephone No. (Include Area Code) 201-316-9365
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 	3. Title Sr. Regulatory Services Associate	
4. Typed Name Robert J. Sloan	5. Date 10/7/05	

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. EPA
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

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

Robert J. Sloan
Performance Chemicals
Regulatory Services

Phone: (201) 316-9365
Fax: (201) 696-3569
bob.sloan@lonza.com

Attention: Emily Mitchell (PM-32)

October 7, 2005

Lonza Formulation I-1.75
EPA Reg. No. 6836-81

NOTIFICATION
THIS SUBMISSION IS NOT SUBJECT TO FEES UNDER PRIA

Dear Emily,

Lonza is submitting a Notification to the subject product's label per PR Notice 98-10. The purpose of the Notification is to restore the option of use of an abbreviated terminal sterilant statement by supplemental registrants of this product.

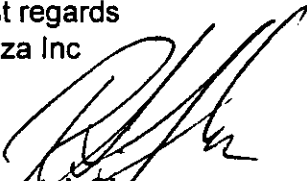
In support of this amendment, enclosed are the following:

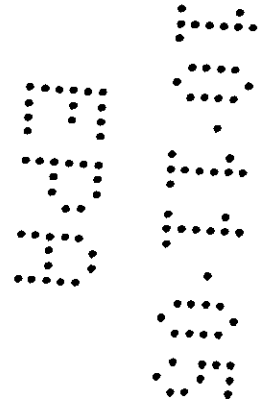
1. EPA Form 8570-1, Application for Pesticide Amendment, OPP ID No. 302577.
2. One copy of an email message dated October 6, 2005 explaining the historical use of the abbreviated statement.
3. Two copies the proposed updated label, with one copy highlighted for ease of review.

This notification is consistent with the provisions of PR Notice 98-10 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 I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions, please call me at 1-800-777-1875, ext. 9365.

Best regards
Lonza Inc


Robert J. Sloan
Sr. Regulatory Services Associate



486

**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 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.

Emergency Information: *(insert telephone number here)*

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

This product is toxic to fish and aquatic organisms. 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 I-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)-Iodine Complex.....	18.05%
(Providing 1.75% titratable iodine)	
Other Ingredients	81.95%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

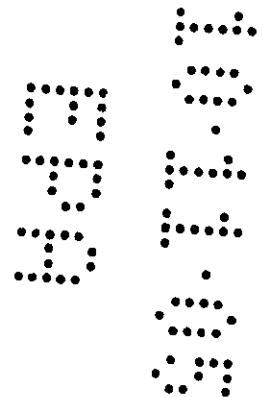
EPA Reg. No. 6836-81

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



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. [optional: 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.

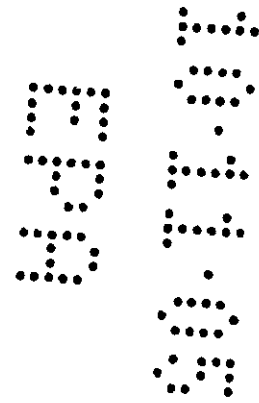
Sanitizing - Meat and food processing equipment and utensils:

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 I-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.

