10/03/2003

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Mr. Robert Sloan Lonza Inc. 17-17 Route 208 Fair Lawn, NY 07410

Subject:

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Lonza Bio-Gentle

EPA Registration No. 6836-38 Resubmission Date: July 9, 2003 EPA Receipt Date: July 10, 2003

Dear Mr. Sloan.

The following amendment submitted in connection with registration under FIFRA, as acceptable for the following reasons.

Response to Agency letter dated June 4, 2003

Conditions

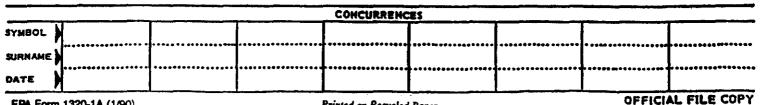
Revise the label as follows:

- Delete the last sentence under the "Directions for Use." You will need to provide the 1. parameters for repeat treatments. Why would you retreat fabric after each washing? How long should repeat treatment continue?
- 2. Add the phrase, "Commercial and Industrial Use Only."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sincerely,

Velma Noble

Product Manager (31)
Regulatory Management Branch I Antimicrobials Division (7510C)

CONCURRENCES								
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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Wear goggles or face shield and protective gloves (rubber, chemical resistant) when handling. May be fatal if absorbed through skin or swallowed. Wash thoroughly with soap and water after handling. 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. Measures against circulatory shock, respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. 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.

PHYSICAL OR CHEMICAL HAZARDS

DO NOT USE OR STORE NEAR HEAT OR FLAME!

LONZA BIO-GENTLE

BACTERIOSTATIC LAUNDRY SOFTENER CONCENTRATE WITH RESIDUAL BACTERIOSTATIC ACTIVITY

Active Ingredients:	
Octyl Decyl Dimethyl Ammonium Chloride	15.0%
Dioctyl Dimethyl Ammonium Chloride	6.0%
Didecyl Dimethyl Ammonium Chloride	9.0%
Other Ingredients:	70.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

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

CAS. NO. MIXTURE

EPA Reg. No. 6836-38 EPA Est. No. (insert EPA Establishment No. here) Net Weight (insert size of container here)

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

ACCEPTED with COMMENTS in EPA Letter Dated:

OCT 3 - 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 68.36 -38 SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DIRECTIONS FOR USE

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

Use 1.00 fluid oz. (2 tablespoons) LONZA BIO-GENTLE per 100 lbs. of fabric (dry weight). Use a maximum of 60 gallons (500 lbs.) of water per 100 lbs. of fabric (dry weight).

To soften laundered fabrics and obtain residual bacteriostatic activity against gram negative and / or gram positive odorcausing bacteria, dilute the appropriate amount of LONZA BIO-GENTLE in one to two gallons of water and then add to the wash-wheel at the beginning of the final rinse cycle.

Repeat the treatment of fabric with LONZA BIO-GENTLE after each washing.

(If 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. Wrap container and put in trash.

(If container size is greater than 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

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 or mixture of 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

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

Do not reuse empty container. Wrap container and put in trash.

FOR HELP IN A CHEMICAL EMERGENCY CALL CHEMTREC 800-424-9300. BEFORE USING CONSULT MATERIAL SAFETY DATA SHEET.

Lonza Bio-Gentle (Alternate Brand name Lonza Bio-Soft) EPA Reg. No. 6836-38 EPA label Amendment 6-28-03

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