

PM 32

6836-85

6/9/97

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Lonza, Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

JUN 9 1997

Attn: Eliot I. Harrison,  
Authorized Agent for Lonza, Inc.

Subject: Lonza TBC-301  
EPA Registration No. 6836-85  
Your Labeling Amendment of September 6, 1996

The submitted labeling amendment, proposing upgraded Precautionary Language in accordance with Acute Toxicity Category II classification has been reviewed. A copy of this review, the Data Evaluation Record (DER), is enclosed. The following remarks are a result of this review.

- The revised labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comment listed below. A stamped copy is enclosed for your records. Submit one copy of the finished printed labeling before releasing the product for shipment.

- Revise the statements of Practical Treatment in the following manner:

**IF SWALLOWED:** Call a Physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. If person is unconscious, do not give anything by mouth.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention.

**IF INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

**IF IN EYES:** Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,

*Robert Travaglini for*

Robert S. Brennis  
Acting Product Manager (32)  
Regulatory Management Branch II  
Antimicrobial Division (7504C)

DESCRIPTION

LONZA TBC-301 is a disinfectant bathroom bowl cleaner, designed for hospital use. This disinfectant toilet bowl cleaner is especially formulated to kill many germs commonly found in hospital, industrial and institutional environments. LONZA TBC-301 is designed for use in toilet bowls and urinals. LONZA TBC-301 contains an acid compatible detergent system that removes resistant stains and increases its disinfectant action. When used as directed, LONZA TBC-301 cleans, disinfects and deodorizes in one easy step.

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND  
DOMESTIC ANIMALS**

**DANGER:** Corrosive. Causes eye damage and skin burns. May be fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing, rubber gloves and safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

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.

**ACCEPTED**  
with **COMMENTS**  
in EPA Letter Data

JUN 9 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, this pesticide  
registered under EPA Reg. No.

6836-85

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**LONZA TBC-301**

High Acid Disinfectant Toilet Bowl Cleaner  
With Organic Soil Tolerance  
For Hospital-Institutional-Industrial Use

Based on a Synergistic Combination of  
Quaternary Ammonium Compounds  
And an Acid Compatible Detergent System  
Disinfects-Cleans-Deodorizes  
Removes Stains and Hard Water Deposits

Active Ingredients

Octyl decyl dimethyl ammonium chloride	0.2250%
Dioctyl dimethyl ammonium chloride	0.0900%
Didecyl dimethyl ammonium chloride	0.1350%
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride	0.3000%
Hydrogen Chloride	9.6000%

Inert Ingredients

89.6500%  
100.0000%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

**STATEMENT OF PRACTICAL TREATMENT**

**If Swallowed:** Call a doctor or get medical attention. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, or if these are not available, drink large quantities of water.  
**If In Eyes:** Hold eyelids open and flush with a steady stream of water for 15 minutes. Get medical attention.  
**If on Skin:** Wash with plenty of soap and water, then cover with moist magnesia or baking soda. Get medical attention.  
**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

SEE LEFT PANEL FOR ADDITIONAL  
PRECAUTIONARY STATEMENTS

<u>EPA Registration No.</u>	6836-85
<u>EPA Establishment No.</u>	6836-IL-1
<u>Net Contents</u>	

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

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RECD EPA/OPP/DPD1

**BEST AVAILABLE COPY**

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### DIRECTIONS FOR USE

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

Flush toilet. Add 3 fluid oz. (6 tablespoons) directly to water in toilet bowl (3/4 gallon). Brush to cover all interior surfaces of the bowl including under the rim. Allow disinfectant solution to remain at least 10 minutes. Flush toilet.

For heavily soiled areas, a preliminary cleaning may be required.

To clean badly stained bowls, repeat above treatment using 5 to 6 fluid ounces of LONZA TBC-301.

For use in urinals, add 3 fluid oz. (6 tablespoons) to 3/4 gallon of water. Apply by brush to all urinal surfaces. Treated surfaces must remain wet for 10 minutes. Flush.

The broad spectrum efficacy of LONZA TBC-301 in toilet bowls and urinals has been evaluated in the presence of 5% serum and found to be effective against the following organisms by the AOAC Use-Dilution test:

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella choleraesuis
- Escherichia coli
- Salmonella typhi
- Serratia marcescens
- Shigella dysenteriae
- Streptococcus faecalis

**BEST AVAILABLE COPY**

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.

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**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.  
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 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. Metal Container: Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (If container is 1 gallon or less, use this container disposal statement). Securely wrap original container in several layers of newspaper and discard in trash.