

6836-85

1/17/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

JAN 17 2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Lonza TBC-301
EPA Registration No.: 6836-85
Application Date: 11/22/2011
Receipt Date: 11/25/2011

Dear Ms. Holcombe:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable.

Proposed Amendment

- Addition of optional Spanish signal word and placeholder for non-FIFRA DOT symbols
- Addition of optional Spanish language and English translation
- Addition of nonrefillable sealed container storage and disposal language

General Comments

A stamped label with is enclosed for your records. 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, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov.

When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline McFarlane
Product Manager (34)

CONCURRENCES

Respiratory Management Branch II
Antimicrobials Division (7510P)

SYMBOL	SURNAME	DATE

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 - *Virucidal

Removes Stains, Rust, Mineral stains, Lime Soap Buildups and Hard Water Deposits

Active Ingredients	
Octyl decyl dimethyl ammonium chloride	0.225%
Dioctyl dimethyl ammonium chloride	0.090%
Didecyl dimethyl ammonium chloride	0.135%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	0.300%
Hydrogen Chloride	9.600%
Inert Ingredients	89.650%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

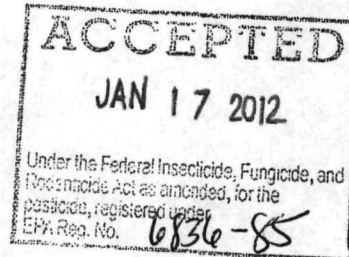
DANGER [PELIGRO]

See left / side / right / back panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-85
EPA Est. No. (insert EPA Est. No. here)
Net Contents (insert container size here)

[DOT Symbols]
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

Manufactured by:
LONZA INC., 90 Boroline Road, Allendale, NJ 07401



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing, and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

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.

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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

{If container size is 5 gallons or greater, use the following Environmental Hazards statements:}

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}

LONZA TBC-301 is a concentrated acid disinfectant bathroom toilet bowl cleaner, especially formulated to kill many germs commonly found in hospital, industrial and institutional environments. **LONZA TBC-301** contains high level of acid together with an acid compatible detergent system, which facilitates the easy removal of resistant stains, Rust, Mineral stains, Lime Soap Buildups and Hard Water Deposits and permits its disinfectant action.

When used as directed, **LONZA TBC-301** cleans, disinfects and deodorizes in one easy step.

*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*

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 for at least 10 minutes. Flush toilet.

To clean badly stained bowls, repeat above treatment using 4 to 5 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. Allow disinfectant solution to remain at least 10 minutes. Flush.

At 3 fluid oz./3/4 gallon of water, **LONZA TBC-301** is effective against a broad spectrum of microorganisms commonly found in toilet bowls and urinals. Effectiveness against *Pseudomonas aeruginosa* [*Pseudomonas*], *Salmonella enterica* [*Salmonella*], *Staphylococcus aureus* [*Staph*], *Shigella dysenteriae*, *Streptococcus faecalis* [*Strep*], *Escherichia coli* [*E. coli*], *Serratia marcescens*, *Salmonella typhi* [*Salmonella*] and HIV-1 [*AIDS virus*] in the presence of 5% serum has been confirmed by the AOAC Use-Dilution procedure.

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids, and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [*HIV-1*] [associated with *AIDS*].

Special Instructions for Cleaning and Decontamination against HIV-1 of Surfaces / Objects Soiled With Blood / Body Fluids

Personal Protection: Clean-up must always be done wearing protective latex gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of **LONZA TBC-301**.

Contact Time: Leave surface wet for one minute. Use a 10 minute contact time for all other bacteria listed.

Disposal of Infectious Material: Blood, body fluids, cleaning materials and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.}

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.

{Metal containers only:} DO NOT cut or weld metal containers.

{Bag in Box Containers:} Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: For Nonrefillable Sealed Containers: Several packaging options are designed in such a way that they cannot be opened (such as a molded plastic bottle with a small opening for dispensing the product). None of these can be triple rinsed because they are essentially closed sealed containers. The following text will be used on these sealed container types:}

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. Wrap empty container and put in trash.