

6836-84

08-31-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

AUG 31 2009

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

SUBJECT: Lonza TBC-302
EPA Registration No.: 6836-84
Amendment Date: June 1, 2009
EPA Receipt Date: June 2, 2009

Dear Ms. Holcombe,

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

Proposed Amendment

- Update Storage and Disposal per PRN 2007-4
- Update Company Address and add optional statements

Conditions

Revise the label as follows:

- 1) The Environmental Hazards must be revised to be in agreement with the ADBAC RED by adding the statement, "*This pesticide is toxic to fish and aquatic invertebrates.*"
- 2) AOAC has updated the species nomenclature for *Salmonella choleraesuis* to *Salmonella enterica*. Revise your label accordingly.
- 3) The "Disposal of Infectious Material" statement under the HIV directions on page 2 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "*must.*"
- 4) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Delete the "Storage and Disposal" Instructions for containers one gallon or less.

CONCURRENCES

SYMBOL	SURNAME	DATE					

3) Revise the "Container Disposal" statements for this product to read:

Container Disposal: Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying.

(Containers 5 gallons or less [please note that the statements are the same for plastic and metal containers])

Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(Container greater than 5 gallons [please note that the statements are the same for plastic and metal containers])

Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

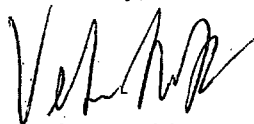
(For Bag in Box Containers): Proposed language acceptable.

General Comments

A stamped copy of the label 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.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

		CONCURRENCES					
SYMBOL	Enclosure: Stamped Label						
SURNAME							
DATE							

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 or using tobacco. 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.

LONZA TBC-302

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 and Hard Water Deposits

Active Ingredients	
Octyl decyl dimethyl ammonium chloride	0.225%
Diocetyl 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	20.320%
Inert Ingredients	<u>78.930%</u>
Total	100.000%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

SEE LEFT / SIDE / RIGHT / BACK PANEL FOR
PRECAUTIONARY STATEMENTS AND FIRST AID

EPA Reg. No. 6836-84
EPA Est. No. *(insert EPA Est. No. here)*
Net Contents *(insert Net Contents here)*
[Country of origin *(insert country)*]
[Manufactured in *(insert country)*]
[Barcode]

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

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

AUG 31 2009

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

6836-84

LONZA TBC-302 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-302** contains high level of acid together with an acid compatible detergent system, which facilitates the easy removal of resistant stains and permits its disinfectant action.

When used as directed, **LONZA TBC-302** cleans, disinfects and deodorizes in one easy step.

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-302**.

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. per 3/4 gallon of water, **LONZA TBC-302** is effective against a broad spectrum of microorganisms commonly found in toilet bowls and urinals. Effectiveness against *Pseudomonas aeruginosa* (*Pseudomonas*), *Salmonella* (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 ~~should~~ 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-302**.

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 ~~should~~ be autoclaved and disposed of according to local regulations for infectious waste disposal.

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~~(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less; Label has any uses other than Household or Residential.)~~

~~STORAGE AND DISPOSAL~~

~~Store in original container in areas inaccessible to children.~~

~~Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap container and put in trash or offer for recycling if available.~~

~~(or)~~

~~Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap container and put in trash or offer for recycling if appropriate.~~

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon.)

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 Containers:) Triple rinse as follows: Fill container 1/4 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:) Triple rinse as follows: Fill container 1/4 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. DO NOT cut or weld metal containers.

(For 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.