

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 3 2003

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

Subject: Formulation DC 100C
EPA Registration No. 6836-101
Amendment Date: July 2, 2003
EPA Receipt Date: July 7, 2003

Dear Mr. Sloan,

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

- Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Revise the "Precautionary Statements" by adding the phrase, "*protective clothing*" and the statement, *Wash thoroughly with soap and water after handling.* Also, delete the last statement, "Do not take internally."
2. Under "General Purpose and Hospital Disinfection" direction, add the statement, "*Allow surfaces to air dry or wipe excess liquid with cloth, mop, or sponge.*" It must appear after the contact time. "
3. Under "General Purpose Disinfection," revise the last sentence of the first paragraph to read "*Rinse all surfaces that come into contact with food such as counters, tables, and stove tops with potable water before reuse. Do not use on utensils, glasses, or dishes.*"
4. Under "General Purpose Disinfection," revise the 2nd and 3rd paragraphs as follows:

Fungicidal Activity: Preclean before disinfecting (following cleaning instructions) To disinfect had nonporous surfaces in locker rooms, shower stalls, walkways around pools and other areas against the pathogenic fungi, *Trichophyton mentagrophytes*, caustive agent of Athletes Foot) , saturate surfaces with 1/4 oz per gallon of water use solution using a mop, brush, sponge, or cloth. Allow surfaces to remain wet for 10 minutes, then air dry.

CONCURRENCES

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Toilet Bowl Disinfection: Remove gross filth. Flush toilet by forcing the bowl water over the trap. Add directly to bowl 2 oz. of product to bowl water. Swab or brush all surfaces thoroughly; especially under the rim. Surfaces must remain wet for 10 then flush.

5. Under "Hospital Disinfection," delete the statement, "...then rinse with a fresh solution containing 2 oz per gallon of water before disinfection."
6. Under "Deodorization," you delete "Formulation C" and replace it with "Formulation DC 100C."
7. Revise the "Sanitization" heading to read "Sanitize Non-Food Contact Surfaces."

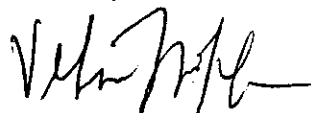
General Comments

Formulation DC 100C is acceptable as this product's new primary brand name.

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.

Sincerely,



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

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield) and protective gloves (rubber or chemical resistant) when handling this product. Remove and wash contaminated clothing before reuse. Do not take internally.

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

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 Dated:

OCT 3 - 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-101

FORMULATION DC 100C

DISINFECTANT - CLEANER - FUNGICIDE

SANITIZER - MILDEWSTAT - DEODORANT

Active Ingredient:

n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆)	
dimethyl benzyl ammonium chloride	5.0%
Other Ingredients:	95.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 6836-101

EPA Est. No. *(insert EPA Est. No. Here)*

NET CONTENTS *(insert container size here)*

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

DIRECTIONS FOR USE

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

FOR CLEANING

Lightly soiled areas-surfaces to be cleaned should be mopped or brushed with a solution containing 1 ounce of Formulation DC 100C per gallon of water. Rinse cleaned area with fresh water.

Heavily soiled areas - mop or brush soiled surface with a solution containing 2 - 3 ounces of Formulation DC 100C per gallon of water. Rinse cleaned surface with fresh water.

GENERAL PURPOSE DISINFECTION

To disinfect walls, floors and other hard nonporous surfaces in homes, schools, restaurants, restrooms and other public areas, mop or brush with a fresh solution containing 1 ounce of Formulation DC 100C per gallon of water so as to maintain thoroughly wetted surface for ten minutes. All soiled surfaces must be precleaned prior to disinfection (follow directions for cleaning). Those surfaces which may later come in contact with food must be rinsed with clear water of drinking quality. Do not reuse solution.

To disinfect hard nonporous surfaces in locker rooms, shower stalls, walkways around pools and other areas against pathogenic fungi, mop or brush with a fresh solution containing 1/4 ounce of Formulation DC 100C per gallon of water so as to maintain thoroughly wetted surface for ten minutes. This solution will destroy *Trichophyton mentagrophytes*, a causative agent of athlete's foot. All soiled surfaces must be precleaned prior to disinfection (follow directions for cleaning). Do not reuse used solution.

To disinfect toilet bowls, flush toilet then force the bowl water over the trap. Add directly to bowl water 2 ounces of Formulation DC 100C. Swab or scrub all surfaces thoroughly including under the rim, and allow to remain wet for at least ten minutes before flushing toilet

HOSPITAL DISINFECTION

To disinfect walls, floors, furniture and other hard non-porous surfaces in hospitals and nursing homes, mop or brush with a fresh solution containing 2 ounces of Formulation DC 100C per gallon of water so as to maintain thoroughly wetted surface for ten minutes. All soiled surfaces must be precleaned prior to disinfection (follow directions for cleaning). Those surfaces that are heavily soiled with blood, fecal material or exudates should be thoroughly scrubbed with a solution containing 2 ounces of Formulation DC 100C per gallon of water, and then rinsed with a fresh solution containing 2 ounces of Formulation DC 100C per gallon of water before disinfection. Do not reuse used solution.

This product has not been tested for effectiveness against *Mycobacterium tuberculosis* and must not be relied upon when tuberculocidal activity is intended by the user.

(Note to reviewer: Only One of the following two statements will 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. This product may be used to preclean 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.

DEODORIZATION

Prior to deodorization of bathroom areas, garbage pails, diaper pails, food storage areas, kennel areas and other areas where obnoxious odors may develop, remove all garbage, refuse, food and/or animals. Preclean surfaces using pressurized water where possible before deodorization. To deodorize, mop or brush surfaces thoroughly with a solution containing 2 ounces of Formulation C per gallon of water,

