

PM 31

6836-101

1174

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 3 - 1995

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

Attention: Eliot I. Harrison
Agent for Lonza

Subject: Formulation DC 100C
EPA Registration No. 6836-101
MOU Compliance Amendment dated January 25, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

1. Under the heading "DIRECTIONS FOR USE", remove the statement "General Classification".
2. Add the restrictive label statement outlined in PR-Notice 94-4: "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".
3. Change Trichophyton interdigitale to Trichophyton mentagrophytes.

A stamped copy of your labeling is enclosed for your records. Submit five (5) copies of the final printed label prior to release of the product for shipment.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

1084

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CAUSES EYE DAMAGE

CAUSES SKIN IRRITATION, ESPECIALLY TO BROKEN SKIN

HARMFUL IF SWALLOWED

Do not get in eyes, on skin or on clothing.
Wear goggles or face shield and rubber gloves when handling this product.
Remove and wash contaminated clothing.
Do not take internally.

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 Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

- Do not contaminate water, food, or feed by storage 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 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.
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.)
Do not reuse empty container (bottle, can bucket). Wrap container and put in trash.

LONZA INC.
17-17 Route 208 - Fair Lawn, NJ 07410
(201)794-2400

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 3 1995

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

6836-101

FORMULATION C

3 of 4

**DISINFECTANT-CLEANER-FUNGICIDE
SANTIZER-MILDF:WSTAT-DEODORANT**

ACTIVE INGREDIENT

n-Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₀) dimethyl benzyl ammonium chloride 5.0%

INERT INGREDIENTS

95.0%

Total

100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush with plenty of water for at least 15 minutes. Call a physician.

IF ON SKIN: Wash thoroughly with soap and water. Remove and wash contaminated clothing before reuse.

IF SWALLOWED: Drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Est. No. 6836-IL-1

EPA Reg. No. 6836-101

NET CONTENTS _____

DIRECTIONS FOR USE

GENERAL CLASSIFICATION

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 C 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 C per gallon of water. Rinse cleaned surface with fresh water.

GENERAL PURPOSE DISINFECTION

To disinfect walls, floors and other hard non-porous surfaces in homes, schools, restaurants, restrooms and other public areas, mop or brush with a fresh solution containing 1 ounce of Formulation C 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 come in contact with food must be rinsed with clear water of drinking quality. Do not reuse solution.

To disinfect hard non-porous 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 C per gallon of water so as to maintain thoroughly wetted surface for ten minutes. This solution will destroy *Trichophyton interdigitale*, 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 C. 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

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 C 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 C per gallon of water, and then rinsed with a fresh solution containing 2 ounces of Formulation C 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.

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. Pre-clean 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.

SANITIZATION

To sanitize walls, floors and other hard non-porous, non-food contact surfaces in the presence of a moderate amount of organic soil, mop or brush with a solution containing 1 ounce of Formulation C per gallon of water so as to maintain thoroughly wetted surface for five minutes. Those surfaces that are heavily soiled must be precleaned prior to sanitization (follow directions for cleaning).

Do not reuse used solution.

MOLD AND MILDEW CONTROL

To control mold and mildew on previously cleaned glass, metal, plastic, tile and other hard non-porous surfaces, mop or brush with a fresh solution containing 2 ounces of Formulation C per gallon of water so as to thoroughly wet all surfaces. Allow to dry on surface. Repeat application weekly or when growth is visible. Do not reuse used solution.

4 of 4

4