

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 20 2004

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

Subject: M3 Formulation #4
EPA Registration No. 6836-309
Amendment Date: March 5, 2004
EPA Receipt Date: March 8, 2004

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below:

- One-year Bacterial Stability Claim

Conditions

Revise the label as follows:

- Page 2: The surface, fiberglass, must be qualified as hard nonporous by listing specific surfaces made of fiberglass; such as fiberglass bathtubs.
- Page 3: Under Disinfection directions, revise the statement, "This product should not be used to clean or disinfect utensils, glassware, and dishes," to read "This product **must not** be used to clean or disinfect utensils, glassware, and dishes."
- Page 3: Remove the parentheses from around the "heavily soiled areas statements." Parentheses are interpreted as optional text, and preliminary cleaning of heavily soiled areas is a requirement for disinfection directions.

Acceptable Data

Data Requirement	Means of Support	Status
Bacterial Stability Use-Dilution Testing - P. aeruginosa	Submitted study, MRID 462198-02	Acceptable: up to 1 yr at 1:54 w/ 10 min. CT and 5% soil load.
Bacterial Stability Use-Dilution Testing- S. choleraesuis	Submitted study, MRID 462198-03	Acceptable: up to 1 yr at 1:54 w/ 10 min. CT and 5% soil load.
Bacterial Stability Use-Dilution Testing - S. aureus	Submitted study, MRID 462198-04	Acceptable: up to 1 yr at 1:54 w/ 10 min. CT and 5% soil load.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

286

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

General Comments

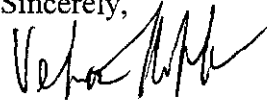
A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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)

Enclosure: Stamped Label
Efficacy Data Evaluation

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

OFFICIAL FILE COPY

3 8 6
HIGHLIGHTED
COPY

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

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves. Harmful if swallowed and/or if absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling poison control center or doctor or going for treatment.

(Note to reviewer: If the container size is 5 gallons or larger, the following Environmental Hazards statements will be used:)

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:

AUG 20 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-309

M3 FORMULATION #4

One-Step Disinfectant - Cleaner - Fungicide
Mildewstat - Virucide* - Deodorizer
for Homes, Hospitals, Institutional and Industrial Use

Effective in hard water up to 400 ppm hardness
(calculated as CaCO₃) in the presence of 5% serum
contamination

Removes Hard Water Deposits, and Lime Soap
Buildups

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	1.50%
Dioctyl dimethyl ammonium chloride	0.60%
Didecyl dimethyl ammonium chloride.....	0.90%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	2.00%
Other Ingredients:.....	95.00%
Total.....	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No. 6836-309

EPA Est. No. (as indicated on container)

Net Contents: (insert container size here)

Manufactured by:

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

M3 FORMULATION #4
EPA Reg. No. 6836-309
EPA draft label 3-6-04

(Note to reviewer: Language in () is optional or interchangeable)

This product contains no phosphorous.

Disinfects (Disinfectant)

Deodorizes (Deodorizer)

Concentrate (Concentrated)

M3 FORMULATION #4:

- will remove hard water deposits and limestone buildups when used as directed.
- is a mild acid pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.
- provides effective cleaning strength in removing difficult to clean soap scum, and hard water deposits.
- improves labor results by effectively controlling malodors.
- delivers disinfectant performance in an economical concentrate.
- is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- is a versatile cleaner and broad spectrum disinfectant formulated for use on non-critical instruments in Ultrasonic Baths (Ultrasonic cleaning units).
- will clean and deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and other places where bacterial growth can cause malodors.

Use M3 FORMULATION #4:

- for cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- to clean and disinfect finished floors, sinks and tubs.
- in hospitals, homes, medical and dental offices, nursing homes, nurseries, public rest rooms, institutions, schools, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, camp grounds, transportation terminals, hotels and motels, business and office buildings.
- on washable hard, nonporous surfaces: floors, walls, countertops, garbage cans, telephones, doorknobs, shower stalls, tubs and tiles, whirlpool bathtub surfaces, toilets, bathtubs, sinks, urinals, toilet bowls, toilet bowl surfaces, other bathroom fixtures, conductive flooring and other hard nonporous surfaces made of metal, glazed porcelain, glazed ceramic, fiberglass, and plastic, porcelain lining, stainless steel, enameled surfaces, finished woodwork, Formica®, vinyl and plastic upholstery.

Cross-contamination is of major housekeeping concern. **M3 FORMULATION #4** has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry.

M3 FORMULATION #4 is a concentrated (one-step) (Hospital Use) disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1, the AIDS virus), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

M3 FORMULATION #4 meets AOAC Use-Dilution Test Standards for hospital disinfectants.

M3 FORMULATION #4 is a (Hospital Use) disinfectant at 1:51 dilution (2.5 oz. per gallon), Bactericidal according to the current AOAC Use-Dilution Test Method and Virucidal* according to the virucidal qualification modified in the presence of 400 ppm hard water plus 5% organic serum against:

(Bacteria:)

Pseudomonas aeruginosa (Pseudomonas)

Staphylococcus aureus (Staph)

Salmonella choleraesuis (Salmonella)

Enterobacter aerogenes (Enterobacter)

Enterococcus faecalis

Enterococcus faecalis- Vancomycin Resistant (VRE)

Escherichia coli (E. coli)

Staphylococcus aureus - Methicillin-Resistant (MRSA)

Staphylococcus aureus - Vancomycin Intermediate Resistant (VISA)

Streptococcus pneumoniae (Strep)

(Viruses:)

*HIV-1 (AIDS Virus)

*Influenza Type A2 / Japan

*Influenza Type B / Hong Kong

M3 FORMULATION #4 is an effective mildewstat and fungicide against *Aspergillus niger* and *Trichophyton mentagrophytes* (the athlete's foot fungus) when used on hard nonporous surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities. This product will effectively inhibit the growth of mold and mildew and the odors caused by them.

DIRECTIONS FOR USE

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

Do not use this product on marble.

Preparation of Use-Solution:

Add (mix) 2.5 oz. per gallon of water (1:51) to disinfect hard, nonporous surfaces.

Disinfection / Virucidal* / Fungicidal / Mold and Mildew Control Directions:

Apply use-solution, with a cloth, mop, sponge or sprayer to thoroughly wet the surface. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with brush, sponge or cloth. Do not breathe spray.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. This product should not be used to clean utensils, glassware and dishes.

(For heavily soiled areas, a preliminary cleaning is recommended.) (For heavily soiled areas and areas with hard water deposits and lime soap buildups, pre-clean the area with the use-solution before disinfection.)

For mold and mildew, repeat when mildew growth returns.

(Note to reviewer: one of the following two statements will be used:)

BACTERICIDAL STABILITY OF USE-DILUTION:

Tests confirm that M3 Formula #4, when diluted in 400 ppm hard water (via use of automatic dispensing devices), remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* for (up to 7 days) (for up to one week) (for up to one month) (for up to 2 months) (for up to 3 months) (up to 4 months) (up to 5 months) (up to 6 months) (up to 7 months) (up to 8 months) (up to 9 months) (up to 10 months) (up to 11 months) (up to 12 months) (up to one year) when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

(or)

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

Foaming Sprayer Directions: Pour concentrate directly into foaming sprayer supply tank. Sprayer must dilute 1 part concentrate to 51 parts water. Spray use-solution directly to surfaces to be cleaned. Scrub to remove buildup using appropriate scrubbing brush or pad. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop.

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must 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 pre-clean 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.

Toilet Bowl and Urinal Disinfectant / Cleaner Directions:

Remove gross filth prior to disinfection.

From Concentrate:

Add 2 oz. to the bowl and mix. Brush over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From Use Solution:

Empty toilet bowl or urinal and apply a 2.5 oz. per gallon use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or mechanical spray. Brush or swab thoroughly, especially under the rim. Allow to stand for 10 minutes and flush.

For Cleaning and Deodorizing: Apply use-solution to hard nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer. Wipe dry with a clean cloth, sponge or mop or allow surfaces to air dry.

Ultrasonic Bath Disinfectant Directions:

Use **M3 FORMULATION #4** to disinfect hard nonporous objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 2.5 oz. per gallon of water (1:51) directly into bath chamber. Preclean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions.

Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

***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 ON 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 **M3 FORMULATION #4**.

Contact time: Leave surface wet for 10 minutes.

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.

(Note to reviewer: If the container is one gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If the container is greater than one gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

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

(Plastic containers): Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke

(Metal Containers): 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.