

6836-309

8/18/2011

1 of 8

Joanna Holcombe
Sr. Commercial Regulatory Service Associate
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

AUG 18 2011

Subject: M3 Formulation #4
EPA Registration No. 6836-309
Amendment Dated: June 06, 2011
EPA Received Date: June 07, 2011

Dear Joanna Holcombe

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable.

Proposed Amendment

- Revised Storage and Disposal sealed container language
- Updating Pathogen Nomenclature
- Revise Note to Reviews
- Adding DOT Symbol

General Comments

A stamped copy of the accepted labels are enclosed for your records. Submit (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. Submit revised labeling for review by the agency. Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2098

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

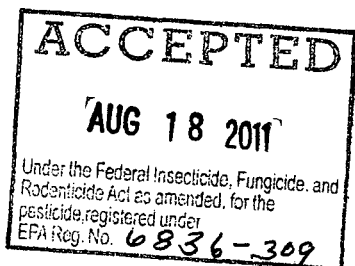
DANGER [PELIGRO]

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)

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

Manufactured by:
Lonza Inc.
90 Boroline Rd.
Allendale, NJ 07401



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.

{Note to reviewer: the following is considered optional marketing language:}

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.

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.

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (*influenza A virus tested and listed on the label*) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

This product has demonstrated effectiveness against (*influenza A virus tested and listed on the label*) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus.

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.

{Note to reviewer: the following is considered optional marketing language:}

Use M3 FORMULATION #4:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use or type of surface. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

- 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 [Bathtubs, Shower stalls, Sinks-bathroom/ kitchen, tubs], plastic, porcelain lining, stainless steel, enameled surfaces, finished woodwork, Formica®, vinyl and plastic upholstery.

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]

Salmonella enterica [Salmonella]

Staphylococcus aureus [Staph]

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 Virus Type A2 / Japan

*Influenza Virus Type B / Hong Kong

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. [of this product] per gallon of water [from cold water tap] [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 must 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 enterica* 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 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.

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.

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

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.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{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.

{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: Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are 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.