

6836-333

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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

SEP - 8 2009

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

Subject: MMR-4U
EPA Registration No.: 6836-333
Amendment Dated: June 8, 2009
EPA Receipt Date: June 10, 2008

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 Container Disposal per PR Notice 2007-4
- Add barcode, country of origin, and manufactured statement

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) The nomenclature for Influenza Type A/Brazil, Vaccinia, Herpes Simplex Type 1, and Herpes Simplex Type 2 is incomplete on pages 7. You need to indicate that the microorganisms are viruses by stating "Influenza *Virus* Type A/Brazil, Vaccinia *Virus*, Herpes *Virus* Simplex Type 1 and 2."
- 3) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Therefore, delete the "Storage and Disposal" statements for containers one gallon or less with uses other than household/residential. Also, revise the first "Note to reviewer to state "For Nonrefillable containers for residential/household uses" and the second "Note to reviewer to state "For

CONCURRENCES

SYMBOL	SURNAME	DATE					

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

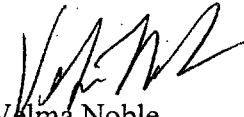
Nonrefillable containers for institutional, /commercial, and industrial uses.”

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 Velma Noble at (703) 308-6233.

Sincerely,



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

Enclosure: Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

MMR-4U

Ready-to-Use
Glass and Surface Cleaner
Hospital Use Disinfectant, Bactericide,
Fungicide, Virucide***, Sanitizer and Deodorizer
For Hospital, Commercial, Institutional, Industrial
and Household Use

Scent Descriptor

Active Ingredients:

n-Alkyl (C ₁₄ -60%, C ₁₆ -30%, C ₁₂ -5%, C ₁₈ -5%)	
Dimethyl Benzyl Ammonium Chloride.....	0.05%
n-Alkyl (C ₁₂ -68%, C ₁₄ -32%) Dimethyl	
Ethylbenzyl Ammonium Chloride	0.05%
Other Ingredients	99.90%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

EPA Reg. No. 6836-333
EPA Est. No. (as indicated on container)
Net Contents: (as indicated on container)
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP - 8 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
6836-333

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

CAUTION. Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FIRST AID

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

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.

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 reviewer: If the container size is 5 gallons or greater, 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 water 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.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

Note to reviewer: The following is considered optional marketing language:

(CLAIMS – NON-FIFRA)

(Note to reviewer: The following claims containing "New" may only be used for a period of six months after EPA's approval of a revised or alternate formula, beginning when the product is first sold or distributed.)

New

New Formula

New Streak-free shine formula

Great on glass

Streak-Free [or Streak Free]

Streak-free Shine

Streak-free Formula

Multi-Surface [Cleaner] [Spray]

Multi-Shine

Multi-Purpose [Spray]

Multi-Purpose [Cleaner] [Spray]

Gives Streak-free shine while it cleans

Sparkling streak-free shine

No dulling residue

No streaking or filming

Leaves no smeary residue

No smeary residue

No residue

No filming

No streaking

Fresh Clean Scent

Fresh Scent

Leaves a Fresh [Clean] Scent

Leaves your house smelling [clean] [and fresh]

Cuts Grease

Cuts Tough Grease

Cuts [tough] [grease] [and grime]

Wipes out tough [grease] [and grime]

Cleans to a streak-free shine [glass], [windows], [mirrors], [faucets], [exterior surfaces of appliances] [stainless steel], [stove tops] [glass furniture], [oven fronts], [exterior surfaces of microwaves], [and shiny surfaces]

Cleans [kitchen] [household] surfaces to a streak-free shine [even glass]

Cleans your whole house and [most] everything in it [to a streak-free shine]

Cleans and deodorizes your whole house

Cleans [kitchens], [bathrooms], [glass], [windows] [mirrors], [appliances] [household surfaces] [and shiny surfaces]

Cleans [kitchens], [bathrooms], [glass], [windows], [mirrors] [shiny surfaces], [and household surfaces] to a streak free shine

Cleans To a Sparkling Shine [Most Everywhere], [Most Hard Nonporous Surfaces], [Most Surfaces], [Most Shiny Surfaces]

No grease [and No Streaks]

Cuts [grease] [and grime], while leaving a streak- free shine

One product to [clean] [and shine] just about any surface

One product to [thoroughly] clean surfaces [throughout the kitchen] [throughout the house] [throughout your bathroom]

No harsh odor
 No overpowering chemical odor
 Leaves your house smelling good
 Leaves your house smelling clean and fresh
 Easy to Use
 Makes life easier
 Easier to clean with one solution [for the whole house] [for multi surfaces]
 The cleaning solution for your busy life
 Makes cleaning easier

(CLAIMS – FIFRA)

Cuts grease, [disinfects], [deodorizes], [sanitizes], and [shines]
 Cuts grease, [Kills Germs(*)], (cleans glass), and shines (surfaces)
 Cuts grease [and grime], [Kills Germs(*)], and [shines]
 Cleans and disinfects hard non-porous household surfaces
 Cleans [and shines], [and disinfects] [hard non-porous household surfaces]
 Cleans, disinfects [hard non porous surfaces], and shines [throughout the house]
 Cleans, disinfects [hard non porous surfaces], and shines quickly and easily
 [Effectively] cleans [even grease] [dirt] [and grime], [windows], [mirrors], [shiny surfaces], [and Kills Germs(*)]
 Cleans, [and] disinfects [hard non porous surfaces], and shines your [shiny] surfaces, [including glass], [including windows], [including mirrors]
 Cleans and disinfects [hard non porous surfaces], [deodorizing], [sanitizing] while leaving a streak-free shine
 Combines a grease cutting formula with antibacterial ingredients [to clean] and [shine]
 Combines antibacterial cleaning with steak-free shine
 Disinfects [as it cleans] [and shines]

Antibacterial [Cleaner] [Spray]
 New Antibacterial
 Antibacterial Multi-Purpose [Cleaner] [Spray]
 Antibacterial Multi-Surface [Cleaner] [Spray]
 Antibacterial Multi-Surface and Glass [Cleaner] [Spray]
 Antibacterial Glass & Surface [Cleaner] [Spray]
 Antibacterial Surface and Glass [Cleaner] [Spray]
 Antibacterial Hard Nonporous Surface and Glass [Cleaner] [Spray]
 3 in 1 Antibacterial Multi-Purpose [Cleaner] [Spray]
 Antibacterial Multi-surface [Cleaner] [Spray]
 Multi-Bacterial
 Multi-Surface Disinfecting [hard non porous surfaces]

Disinfectant
 Disinfects
 Kills Germs(*)
 Kills 99.9% of Germs(*)
 Kills more than 99.9% of household germs(*)
 Sanitizes
 Sanitizing
 Sanitization

Bactericidal cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry.

MMR-4U has been formulated to aid in the control of cross-contamination from treated surfaces in these areas.

MMR-4U is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria.

When used as directed **MMR-4U** will 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 mal odors.

MMR-4U is for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, athletic facilities, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels.

MMR-4U uses an anti-bacterial formula to cut grease, grime and to disinfect.

MMR-4U Kills Germs(*) such as Staphylococcus aureus, Salmonella enterica and Pseudomonas aeruginosa.

MMR-4U removes dirt and grime and Kills Germs(*)

MMR-4U Kills Germs(*) and bacteria and cuts grease and grime.

MMR-4U disinfects and deodorizes.

MMR-4U cleans tough dirt while leaving a fresh, clean, scent.

MMR-4U cleans and deodorizes.

MMR-4U cuts grease and deodorizes.

MMR-4U cuts grease, grime and deodorizes.

For use in households.

Contains cleaning agents, perfume, dye and water.

MMR-4U cleans and deodorizes and cuts grease and grime.

MMR-4U is a no-rinse cleaner that disinfects, cleans and deodorizes in one labor saving step.

MMR-4U cleans, shines, deodorizes and disinfects hard, non-porous household surfaces.

MMR-4U is for use in kitchens, bathrooms, and other household areas.

MMR-4U kills household germs in 10 minutes; effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella enterica.

MMR-4U is a multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors, Plexiglas, Lexan, and other glass surfaces.

Use **MMR-4U** on the multi-touch surfaces responsible for cross-contamination.

Use **MMR-4U** on tables, chairs, basins, countertops, bed rails, door knobs and handles, glass surfaces including windows and mirrors.

MMR-4U combines streak-free cleaning and hospital disinfectancy with no compromise in performance.

MMR-4U is a glass cleaner, and disinfectant all in one.

MMR-4U kills Staphylococcus aureus and Salmonella enterica.

MMR-4U (Note to reviewer: Language in [] is optional or interchangeable. "()", "****" or "*****" may be interchanged)

EPA REG. NO. 6836-333

EPA Stamped 01/15/09, Draft 6-3-09

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MMR-4U CONCENTRATE is an effective fungicide against Trichophyton mentagrophytes [the athlete's foot fungus] when used in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

MMR-4U kills odor causing bacteria that cause bad odors.

MMR-4U disinfects!

MMR-4U cleans and disinfects.

MMR-4U cleans soils and disinfects germs.

MMR-4U leaves a fresh clean scent.

MMR-4U maximizes labor results by effectively controlling odors.

MMR-4U is for non-scratch cleaning of showers and tubs, shower doors and curtains and bathroom fixtures.

MMR-4U may be used in:

- hospitals, nursing homes, medical and dental offices and clinics, operation rooms, isolation wards, and medical research centers.
- day care centers and nurseries.
- restaurants and bars, cafeterias, institutional kitchens, fast food operations.
- supermarkets, convenience stores, retail and wholesale establishments, dressing rooms, and laundries.
- crime scenes and funeral homes.
- institutional facilities, laboratories, factories, business and office buildings, restrooms, hotels and motels, and transportation terminals.
- kitchens, bathrooms, and other household areas.
- institutions, schools and colleges, classrooms, athletic facilities and locker rooms.
- camp grounds, play grounds, and recreational facilities.
- household and automotive garages, boats, ships, mobile homes, trains, and airplanes.
- all public places where cleanliness and bacterial control are vital aspects of the environmental sanitation program; and any commercial, industrial, or institutional facility where a clean and sanitary environment is important.

MMR-4U may be used on washable hard nonporous surfaces including:

- non-food contact counter tops, sinks, refrigerator exteriors, coolers, freezers, stovetops, exterior surfaces of appliances, non-food contact equipment, shelves, racks and carts.
- picnic tables and outdoor furniture.
- telephones and computers/keyboards.
- tables, chairs, desks, bed frames, walls, cabinets, doorknobs, and garbage cans.
- highchairs and baby toys.
- drinking fountains.
- shower stalls, shower doors and curtains, tubs and glazed tiles,
- fiberglass sinks**, tubs and showers
- glazed porcelain tiling, restroom fixtures and toilet bowl exteriors.

- windows and mirrors.
- glass, metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, sealed granite, sealed marble, plastic, chrome and vinyl.

Note: MMR-4U will not harm most washable surfaces. However, on painted surfaces and wall coverings test a small area before use. If applied to aluminum, [copper or brass,] wipe dry immediately.

Note: Repeated use on copper or brass may discolor these surfaces.

Note: Do not use on copper or brass as repeated use can discolor these surfaces.

MMR-4U is a Hospital Use Disinfectant, is Bactericidal according to the AOAC Germicidal Spray Products Test Method, Virucidal*** according to the virucidal qualification, Fungicidal according to the AOAC fungicidal test, modified in the presence of 5% organic serum and 400 ppm hard water against the following bacteria, viruses and fungi:

or

(*)Effective (in 10 minutes) against: [select from organisms listed below]

(Bacteria:)

Pseudomonas aeruginosa [Pseudomonas]

Staphylococcus aureus [Staph]

Salmonella enterica [Salmonella]

E. coli 0157:H7 [pathogenic E. coli]

Enterobacter aerogenes

Klebsiella pneumoniae

Methicillin-resistant Staphylococcus aureus [MRSA]

Vancomycin-resistant Enterococcus faecalis [VRE]

Proteus vulgaris

Pseudomonas cepacia

Shigella dysenteriae

Serratia marcescens

Staphylococcus epidermidis

Streptococcus pyogenes

***(Viruses:)

Influenza A₂ Hong Kong (Influenza)

Respiratory Syncytial Virus (RSV)

Vaccinia (Pox Virus)

Herpes Simplex Type 1 (Herpes)

Herpes Simplex Type 2 (Herpes)

HIV-1 (AIDS virus)

(Fungi:)

Trichophyton mentagrophytes [Athlete's Foot Fungus]

MMR-4U is a sanitizer for non-food contact surfaces in the presence of 400 ppm hard water plus 5% organic serum in 5 minutes against:

Klebsiella pneumoniae

Staphylococcus aureus

Directions for Use:

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

(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.

Do not breathe spray.

[General] [Cleaning] [Surface] [and] [Glass] Directions:

[1] [Turn] [Rotate] nozzle to "On" [position]

[2] [Hold] [Spray] 6-8 inches from surface.

[3] Wipe with a [dry] paper towel or [lint free] cloth [to a streak free shine.] [No rinsing necessary.]

or

[General] [Cleaning] [Surface] [Glass] (Directions):

Spray 6-8 inches from hard, non-porous [and] [glass] surfaces. Wipe with a [dry] paper towel or [lint free] cloth [to a streak free shine]. [No rinsing necessary.]

To [(Disinfect) (/) [(Sanitize) (/) [(Deodorize):

For heavily soiled areas, a precleaning is required. For hard nonporous surfaces, spray [6 - 8 inches from surface] until thoroughly wet.

To Sanitize: Let stand 5 minutes before wiping.

To Disinfect: Let stand for 10 minutes before wiping. A potable water rinse is required for surfaces in direct contact with food. Do not use on drinking glasses, dishes and utensils.

or

To Disinfect: Clean surfaces prior to disinfecting heavily soiled areas. Thoroughly wet hard non-porous surfaces with [disinfecting solution] [this product] for 10 minutes before wiping. A potable water rinse is required for surfaces in direct contact with food. Do not use on drinking glasses, dishes and utensils.

or

Sanitizing [Non-Food Contact Surface] Directions: Spray MMR-4U to sanitize hard, non-porous [environmental] surfaces. Treated surfaces must remain wet for 5 minutes. Wipe dirt away with a [dry] paper towel or [lint free] cloth.

Note to reviewer: These Use Sites may be depicted by Pictures:

[Bathroom], [Glass furniture], [Kitchen(**)], [Car window], [Window], [Mirror], [Appliances(**)], [Outdoor grill], [Patio Furniture], [Floor], [Garbage can], [Pet area], [Wall], [Glass Surfaces], [Other Surfaces]

(**)A rinse is required for surfaces in direct contact with food.

[Refill:

- Refill 32 oz. sprayer size from this convenient refill container.
- Use only in MMR-4U spray bottle.
- Do not dilute]

KILLS HIV ON PRECLEANED 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 on 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 must always be done wearing protective gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of **MMR-4U**.

Contact Time: Leave surface wet for 1 minute. Use a 10 minute contact time for all other bacteria, viruses and fungi listed on this label.

Disposal of Infectious Materials: Blood, body fluids, cleaning materials and other clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

(Note to reviewer: For Containers ~~one gallon or less~~. The nonrefillable container statement will be removed when directions for how the pesticide user refills the container are included:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

(Nonrefillable container:) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for recycling if available.

(or)

(Nonrefillable container:) Do not reuse or refill this container (except as described in the directions for use). Wrap [container] and put in trash or offer for reconditioning if appropriate.

(Note to reviewer: For Containers ~~over one gallon~~. The nonrefillable container statement will be removed when directions for how the pesticide user refills the container are included:)

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 (except as described in the directions for use).

(Plastic Containers:) 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 Containers:) Triple rinse (or equivalent). Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. DO NOT cut or weld metal containers.