

47371-97

11/24/2010

1 of 10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Joanna Holcombe,
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401, USA

NOV 24 2010

Subject: Product Name: Formulation RTU-90
EPA Reg. No.: 47371-97
Notification Date: August 25, 2010
EPA Receipt Date: August 27, 2010
Submission #: 881169

Dear Ms. Holcombe,

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

Proposed Amendment

- Add Universities as an area of use
- Correct the HIV personal protection statement
- Add an optional graphic

General Comments:

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

Should you have any questions or comments concerning this letter, please contact Velma Noble PM Team 31 at (703) 308-6233.

Sincerely,

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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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

CAUTION. Harmful if absorbed through the skin. Avoid contact with skin, 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. 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.

(If container size is 5 gallons or greater, use the following Environmental Hazards statements :)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. 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.)

- Disinfects (Disinfectant)
- Cleans (Cleaner)
- Deodorizes (Deodorant)
- This product contains no (phosphates or) phosphorous (compounds).
- Ready-to-Use
- Citrus Scent
- Fresh Mild Scent
- (Convenient) Ready To Use formula.
- (Economical) (Spray & Wipe) formula.
- Kills odor-causing bacteria.
- Inhibits (the growth of) (mold) (and) (mildew)
- Kitchen, Bathroom, Household Disinfectant Cleaner.
- Leaves (your house with) a (clean) (fresh) scent.
- Trigger spray(er)
- Pump spray(er)

(Note to reviewer: the following is considered optional marketing language:)

FORMULATION RTU-90

- (not only) helps control the hazards of cross-contamination on treated hard, nonporous, environmental surfaces (but also)
- kills many microorganisms that cause odors
- for disinfecting hard, nonporous, surfaces
- is formulated for use in the household (homes), schools, colleges, universities and office buildings, health care facilities, medical and dental offices, nursing homes, airports, and federally inspected meat and poultry plants
- delivers non-acid disinfectant and cleaning performance.
- is effective yet economical.
- kills household germs; effective against *Pseudomonas aeruginosa* (*Pseudomonas*), *Staphylococcus aureus* (*Staph*) and *Streptococcus pyogenes* (*Strep*), *Influenza A/Brazil Virus (influenza) and *Trichophyton mentagrophytes* (*Athlete's foot fungus*) (cause of Ringworm).
- effective against the pathogenic fungi *Trichophyton mentagrophytes* (*Athlete's Foot Fungus*) (cause of Ringworm) when used as directed for disinfection with a contact time of 10 minutes on hard, nonporous surfaces in bathrooms, including shower stalls, floors, bath mats, glazed bathroom tiles and locker room benches.
- effectively inhibits the growth of mold and mildew, plus the odors caused by them
- cleans, disinfects and deodorizes in one labor saving step.
- can be used with a mop and bucket, trigger sprayers, sponge or by soaking.
- (improves labor results by) effectively controls (controlling) malodors.
- deodorizes by killing microorganisms that cause offensive odors.
- will disinfect, clean and deodorize surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- 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 complete, chemically balanced disinfectant.
- will not leave grit or soap scum.
- as a disinfectant on hard, nonporous surfaces.
- is a (versatile) cleaner and broad spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths (Ultrasonic cleaning units).
- is a (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.
- meets AOAC efficacy standards for hospital disinfectants.

Use Formulation RTU-90

- in federally inspected Meat & Poultry Plants as a disinfectant or non-food contact sanitizer on all surfaces in inedible product processing areas, nonprocessing areas and / or exterior areas. This product was authorized by USDA as category C1 under the prior authorization program and its formula has not been changed.
- in kitchens, bathrooms and other household areas.
- to clean and disinfect finished floors, sinks and tubs.
- with a mop and bucket, trigger sprayer, sponge or by soaking.
- for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- for disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.
- to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for disinfection.

(Note to reviewer: the following is considered optional marketing language:)

FORMULATION RTU-90 is a mildewstat and will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard nonporous surfaces.

Cross-contamination is of major housekeeping concern. FORMULATION RTU-90 has been formulated to aid in the reduction of cross-contamination in not only in hospitals, but in schools, institutions and industry.

KITCHEN: Kitchen floors collect both traffic dirt and kitchen germs. Use anywhere greasy dirt is a problem.

BATHROOM: Great for cleaning and deodorizing basins, tubs, and glazed tiles. Leaves everything bright and clean, kills odor-causing bacteria. Odors disappear instantly. Use where odors are a problem.

FORMULATION RTU-90 is a (one-step) (Hospital use) disinfectant, Bactericidal according to the current AOAC Use-Dilution Test Method, Fungicidal according to the AOAC Fungicidal Test and Virucidal* according to the virucidal qualification modified in the presence of 5% organic serum against:

(or)

Kills:

(Bacteria:)

Pseudomonas aeruginosa (*Pseudomonas*)

Staphylococcus aureus (*Staph*)

Salmonella enterica (*Salmonella*)

Streptococcus pyogenes (*Strep*)

(Viruses:)

*Herpes Simplex Virus Type 2 (*Herpes*)

*HIV-1 (the AIDS Virus)

*Influenza Type A / Brazil Virus (*Influenza*)

(Fungi:)

Aspergillus niger

Trichophyton mentagrophytes (*Athlete's Foot Fungus*)
(Cause of Ringworm)

- 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.

(Note to reviewer: The following is considered optional marketing language.)

(AREAS OF USE:)

Use Formulation RTU-90 in:

- | | | |
|---|-------------------------------|--------------------------|
| Bathrooms | Athletic facilities | Camp grounds |
| Homes (households) | Barber shops | Play ground equipment |
| Kitchens | Business and office buildings | |
| | Colleges | Airports |
| Dental offices | Correctional facilities | Airplanes |
| Health Care Facilities | Dressing rooms | Boats |
| Hospitals | Exercise facilities | Buses |
| Medical Offices | Factories | Campers |
| Nursing homes | Hotels | Cars |
| | Institutional facilities | Emergency vehicles |
| Day care centers | Institutions | Mobile homes |
| Nurseries | Locker rooms | Ships |
| | Motels | Taxis |
| Convenience stores | Prisons | Trailers |
| Food processing plants | Public facilities | Trains |
| Food storage areas | Public rest rooms | Transportation terminals |
| Institutional kitchens | Schools | |
| USDA inspected food processing facilities | Shower and bath areas | |
| | Salons | |
| | <u>Universities</u> | |

(TYPES OF SURFACES:)

Use Formulation RTU-90 on washable hard, nonporous surfaces of:

- | | | |
|---|--|--|
| Appliances | Outdoor furniture | Other hard nonporous surfaces made of: |
| Bathroom bowls | Exterior Surfaces of residential Refrigerators | Formica® |
| Bathroom basins | Commercial Refrigerators | Glazed ceramic |
| Bathroom fixtures | | Glazed enameled surfaces |
| Bathtubs | Refrigerated storage and display equipment | Glazed porcelain |
| Cabinets | Showers | Metal |
| Chairs | Shower stalls | Plastic (such as polystyrene or polypropylene) |
| Coils and drain pans of air conditioning and refrigeration equipment and heat pumps | Sinks (bathroom, kitchen) | Sealed stone |
| Conductive flooring | Stoves (stovetops) | Stainless steel |
| Counters (countertops) | Tables, (picnic tables) | Upholstery, vinyl and plastic |
| Countertop laminates | Telephones | Woodwork, finished |
| Desks | Toilets | |
| Doorknobs | Toilet bowls | |
| Fiberglass bathtubs | Toilet bowl surfaces | |
| Fiberglass sinks | Tubs | |
| Floors | Tiles, glazed | |
| Garbage cans | Ultrasonic baths | |
| Highchairs | Urinals | |
| | Walls | |
| Exterior Surfaces of residential Microwave ovens | | |
| Commercial Microwave Ovens | | |

DIRECTIONS FOR USE

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

DISINFECTION / *VIRUCIDAL / FUNGICIDAL / MOLD & MILDEW DIRECTIONS: If surfaces are visibly dirty preclean first.

(Note to reviewer: The following directions are for products not sold directly in spray bottles:)

(Apply **Formulation RTU-90** with a mop, sponge, cloth, or sprayer on hard, nonporous surfaces to thoroughly wet surfaces. For sprayer applications use a coarse spray device. Spray 6 - 8 inches from surface. Avoid breathing spray.)

(Note to reviewer: Alternate directions for products sold directly in spray bottles:)

(Spray 6 - 8 inches from surface, until surfaces are thoroughly wet.)

Rub with a brush, sponge or cloth. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth, or sponge or allow to air dry. Rinsing is not necessary on floor surfaces that are to be waxed or polished.

For mold and mildew control, repeat application weekly or when growth reappears.

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.

(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.

TO CLEAN AND / OR DEODORIZE: Apply by mop, sponge, cloth or spray on hard, nonporous surfaces. Wipe dry with a clean cloth, or sponge, or allow to air dry.

SANITIZING NON-FOOD CONTACT SURFACES: Use on washable, hard, nonporous surfaces: walls, floors, tables, garbage cans and telephones. The product is effective against *Staphylococcus aureus* and *Enterobacter aerogenes* in the presence of 5% serum. Apply by mop, sponge, cloth or spray to thoroughly wet surfaces for a minimum contact time of 5 minutes. Wipe dry with a clean cloth or sponge, or allow to air dry. Do not use in food preparation, food handling and food storage areas. Do not use to sanitize glassware, dishes or utensils.

TO CLEAN AND DISINFECT TOILET BOWLS AND URINALS: Remove gross filth from bowl. Remove or expel over the inner trap residual bowl water. Use 4 ounces of product in toilet bowl or urinal. Apply (squeeze) directly around bowl and under rim; then brush or swab thoroughly. Allow product to remain on surface for a contact time of 10 minutes; then flush toilet. This product, when used as directed, will not harm white or colored bowls or inanimate, hard surfaces. Close cap on container after use.

FOR USE ON FINISHED FLOORS: Apply with a damp mop or autoscrubber. Allow surface to remain wet for 10 minutes. Wipe or allow to air dry.

SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION (BACTERICIDE) / VIRUCIDE / FUNGICIDE DIRECTIONS:

Use **FORMULATION RTU-90** undiluted to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Use fresh product daily or more often if product becomes diluted or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

ULTRASONIC BATH DISINFECTANT DIRECTIONS:

Use **FORMULATION RTU-90** to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour **FORMULATION RTU-90** directly into bath chamber. Pre-clean 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. Use fresh product for each use.

VEHICLES: Clean all vehicles including mats, crates, cabs and wheels with **FORMULATION RTU-90**. Then apply **FORMULATION RTU-90** as is to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

KILLS HIV-1 (AIDS VIRUS) 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 of inanimate surfaces / objects with blood or body fluids, and in which the surface / 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 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal Protection: ~~Clean-up must always be done wearing protective gloves, gowns, masks and eye protection~~

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

Contact Time: Effective against HIV-1 (AIDS virus) on hard, nonporous surfaces in the presence of a moderate amount of organic soil (5% blood serum) (providing 1800 ppm of active quaternary) for a contact time of 5 minutes at room temperature (20 - 25°C). Use a ten (10) minute contact time for disinfection against all other bacteria, fungi and viruses claimed.

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

FOR USE IN FEDERALLY INSPECTED MEAT AND POULTRY PLANTS: For use on all surfaces in inedible product processing areas non-processing areas and/or exterior areas. Before using this product, food products and packaging materials must be removed or carefully protected, then follow the "Disinfection Directions" above.

(Note to reviewer: For Nonrefillable Containers, Ready to Use Household/Residential Use Products)

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: Nonrefillable Containers, Ready-To-Use Products for Commercial/Institutional/Industrial Uses)

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.

(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.

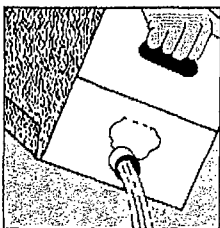
(For Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

(Note to reviewer: The following is an optional proprietary graphic)

ACTION PAC®

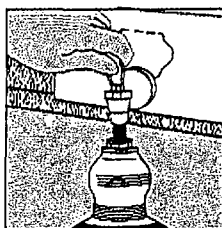
Dispensing Unit: easy to store, easy to pour container

Sistema distribuidor ACTION PAC® fácil de almacenar, recipiente fácil de llenar



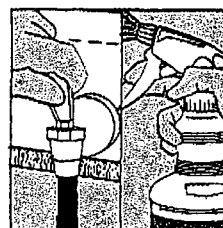
Two comfort grip handles for pouring

Dos cómodas asas de agarre para verter



Stores on shelf for dispensing. Quick-Draw® spigot (Available separately)

Se guarda en el estante para verter. Grifo Quick-Draw (Disponibles por separado)



Quick-Draw® spigot and Grip & Go® (Available separately)

Grifo Quick-Drawy Grip & Go! (Disponibles por separado)