

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

47371-97

10/03/2003

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OCT - 3 2003

Mr. Robert Sloan  
H&S Chemical Division of Lonza  
17-17 Route 208  
Fair Lawn, NJ 07410

Subject: Formulation RTU 90  
EPA Registration No. 47371-97  
Resubmission Date: July 8, 2003  
EPA Receipt Date: July 8, 2003

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable for the following reasons.

- Response to Agency letter dated June 26, 2003

**Conditions**

Revise the label as follows:

Page 3: Under "Bathrooms," qualify the surface, "tile," as hard, nonporous by stating "glazed" tile.

**General Comments**

A stamped copy of the labeling 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 Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

**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**

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.

**FORMULATION RTU-90**

**ONE STEP - VIRUCIDAL  
READY TO USE GERMICIDE  
CLEANER— DISINFECTANT— DEODORANT**

**CITRUS / FLORAL / PINE / MINT / LEMON /  
FRESH / CLEAN (SCENT) (ODOR)  
(FRAGRANCE)**

**Active Ingredients:**

n-Alkyl (C <sub>14</sub> 60%, C <sub>16</sub> 30%, C <sub>12</sub> 5%, C <sub>18</sub> 5%)	
dimethyl benzyl ammonium chloride.....	0.09%
n-Alkyl (C <sub>12</sub> 50%, C <sub>14</sub> 30%, C <sub>16</sub> 17%, C <sub>18</sub> 3%)	
dimethyl ethylbenzyl ammonium chloride.....	0.09%
Other ingredients.....	<u>99.82%</u>
Total.....	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

EPA Reg. No. 47371-97  
EPA Est. No. *(as indicated on container)*  
NET CONTENTS *(as indicated on container)*

H&S CHEMICALS DIVISION  
c/o Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

**OCT 9 - 2003**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 47371-97

(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)

**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
- is recommended for disinfecting hard, nonporous, surfaces
- is formulated for use in the household (homes), schools, colleges 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 (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.

**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 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 choleraesuis (Salmonella)
- Streptococcus pyogenes (Strep)

(Viruses:)

- \*Herpes Simplex Virus Type 2 (Herpes)
- \*HIV-1 (the AIDS Virus)
- \*Influenza Type A / Brazil (Influenza)

(Fungi:)

- Aspergillus niger
- Trichophyton mentagrophytes (Athlete's Foot Fungus)  
(Cause of Ringworm)

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

**(AREAS OF USE:)**

Use Formulation RTU-90 in:

Bathrooms  
Homes (households)  
Kitchens

Dental offices  
Health Care Facilities  
Hospitals  
Medical Offices  
Nursing homes

Day care centers  
Nurseries

Convenience stores  
Food processing plants  
Food storage areas  
Institutional kitchens  
USDA inspected food processing facilities

Airports  
Athletic facilities  
Barber shops  
Business and office buildings  
Colleges  
Correctional facilities  
Dressing rooms  
Exercise facilities  
Factories  
Hotels  
Institutional facilities  
Institutions  
Locker rooms  
Motels  
Prisons  
Public facilities  
Public rest rooms  
Schools  
Shower and bath areas  
Salons

Camp grounds  
Play ground equipment

Airports  
Airplanes  
Boats  
Buses  
Campers  
Cars  
Emergency vehicles  
Mobile homes  
Ships  
Taxis  
Trailers  
Trains  
Transportation terminals

**(TYPES OF SURFACES:)**

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

Appliances  
Bathroom bowls  
Bathroom basins  
Bathroom fixtures  
Bathtubs  
Cabinets  
Chairs  
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps  
Conductive flooring  
Counters (countertops)  
Countertop laminates  
Desks  
Doorknobs  
Fiberglass bathtubs  
Fiberglass sinks  
Floors  
Garbage cans  
Highchairs  
Microwave ovens (Exterior Surfaces of residential)  
Microwave Ovens (commercial)  
Outdoor furniture

Refrigerators (Exterior surfaces of residential)  
Refrigerators (Commercial)  
Refrigerated storage and display equipment  
Showers  
Shower stalls  
Sinks (bathroom, kitchen)  
Stoves (stovetops)  
Tables, (picnic tables)  
Telephones  
Toilets  
Toilet bowls  
Toilet bowl surfaces  
Tubs  
Tiles, glazed  
Ultrasonic baths  
Urinals  
Walls

Other hard nonporous surfaces made of:  
Formica®  
Glazed ceramic  
Glazed enameled surfaces  
Glazed porcelain  
Metal  
Plastic (such as polystyrene or polypropylene)  
Sealed stone  
Stainless steel  
Upholstery, vinyl and plastic  
Woodwork, finished

**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:** Disposable protective gloves, gowns, face masks, or eye coverings, as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

**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 should 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.

*(If container size is one gallon or less, use the following Storage and Disposal statements.)*

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to small children. Do not reuse empty container. Wrap and discard in trash or recycle.

*(If container size is greater than one gallon, use the following Storage and Disposal statements.)*

**STORAGE AND DISPOSAL**

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

**Pesticide Storage**

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side-walls.

**Pesticide Disposal**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Disposal**

*(Metal containers)* Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

*(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.