

47371-97

2-29-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

FEB 29 2000

ATTENTION: Ruth Trager

SUBJECT: Formulation RTU-90  
EPA Registration Number 47371-97  
Your Amendment Dated: December 1, 1999  
EPA Received Date: December 2, 1999

The amendment referred to above, submitted in connection with registration under FIFRA as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. In the left column on page one under "Kitchen" revise as follows: "Kitchen floors collect both traffic dirt and *kitchen* germs."

B. As per DIS/TSS-15 revise the directions for "Disinfection/Viricidal/Fungicidal" to begin with the following statement: "*Remove gross filth or heavy soil.*"

C. Revise the directions for use on toilet bowls to begin with the heading "To Clean and Disinfect Toilet Bowls *and Urinals*"

Revise the remainder of this section as follows: "*Remove gross filth from bowl. Remove or expel over the inner trap any residual bowl water. Use 4 ounces of product in the toilet bowl or urinal. Apply (squeeze) directly around the bowl and under the rim. Then scrub thoroughly with brush. Allow product to remain on surface for a contact time of ten minutes. Then flush toilet. This product, when used as directed, will not harm white or colored bowls or inanimate, hard nonporous surfaces. Close cap on container after use.*"

CONCURRENCES

SYMBOL	7510C						
SURNAME	J. Lentz						
DATE	2/29/00						

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D. Revise the "Mildewstatic Instructions" as follows: "...when applied to hard, nonporous surfaces listed on this label. Apply with a cloth..."

E. Revise the Ingredients Statement to include the phrase "Total.....100%"

F. The Agency reviewed data supplied on this product to establish a Toxicity Profile in 1984. A copy of this review is enclosed. Your product received toxicity category III for acute dermal toxicity. Therefore your label must include a "Precautionary Statement" as well as a "First Aid" statement. The following language must be included in the "Precautionary Statement":

"Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling."

Include the following information in the "First Aid" statement:

"IF ON SKIN: Wash with plenty of soap and water. Get medical attention."

G. Revise the first statement in the center column on page one as follows: "Not only helps control the hazards of cross-contamination on treated hard, nonporous environmental surfaces, but..."

H. Revise your label to list the correct name of the organism which causes Athlete's Foot Fungus: Trichophyton mentagrophytes. In addition, as per Subdivision H Section 101-3 include the following directions for use of this product as a fungicide: "This product is effective against the pathogenic fungi Trichophyton mentagrophytes (Athlete's Foot Fungus) when used as directed for disinfection with a contact time of 10 minutes on hard nonporous surfaces in bathrooms including shower stalls, floors, locker room benches, bath mats and glazed bathroom tiles."

I. On page 1, the left column, revise the "Pesticide Storage" statement for containers larger than 1 gallon to include "Store in original container in areas inaccessible to children."

J. Make the following revisions to center column on page one:

- A. "...cabinets, doorknobs, telephones, shower stalls, tubs and glazed ceramic tile..."
- B. "...toilet bowl surfaces, glazed porcelain tiling, enameled surfaces, finished woodwork, Formica® vinyl and plastic upholstery..." deleting the reference to "leather" which is a porous surface.
- C. Delete the reference in this section to the phrase "related fixtures" which follows "toilet bowl surfaces." This phrase is too broad.
- D. Delete the reference in this section to "stone" which is a porous surface.

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K. The following section of your label must be in all capital letters: "KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS"

2. Submit two ( 2 ) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosures (Toxicity Review and Stamped Label)  
7510C:T.Lantz:2/28/00:47371-97

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FEB 29 2000

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

47371-97

**FORMULATION RTU-90**  
**ONE STEP - \*VIRUCIDAL / FUNGICIDAL**  
**READY TO USE GERMICIDE**  
**CLEANER--DISINFECTANT--DEODORANT**

**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.

**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.

\*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 latex or vinyl 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.

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.

**KITCHEN:** Kitchen floors collect both traffic dirt and 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 household germs. Odors disappear instantly. Use where odors are a problem.

**DIRECTIONS FOR USE**

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

**DISINFECTION / \*VIRUCIDAL / FUNGICIDAL DIRECTIONS:** Apply by mop, sponge, cloth, or spray on hard nonporous surfaces to thoroughly wet surfaces for a minimum contact time of ten 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. 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 sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surfaces, rub with brush, sponge or cloth. Avoid breathing spray.

**TO CLEAN AND DISINFECT TOILET BOWLS:** Remove or expel over the inner trap residual bowl water. Use 4 ounces of product in toilet bowl. Apply (Squeeze) directly around bowl and under rim. Then scrub thoroughly with brush. This product, when used as directed, will not harm white or colored bowls or inanimate, hard surfaces. Close cap on container after use. For urinals add 4 ounces of product. Then scrub thoroughly with a brush for a contact time of ten minutes.

**MILDEWSTATIC INSTRUCTIONS:** Will effectively inhibit the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops. Apply with cloth, sponge, mop or spray, making sure to wet all surfaces completely. Allow surfaces to remain wet for 10 minutes; let air dry. Repeat application weekly or when growth reappears.

**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.

Not only helps control hazard of cross-contamination from treated surfaces on hard, nonporous, environmental surfaces, but also kills many microorganisms that cause odors. Recommended for disinfecting hard, nonporous, inanimate surfaces. 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.

Use on the following washable hard nonporous surfaces: floors walls, countertops, stovetops, exhaust fans, sinks, appliances, refrigerators, tables, picnic tables, outdoor furniture, chairs, desks, telephones, garbage cans, highchairs, washable walls, cabinets, doorknobs, telephones, tubs and tiles, bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, porcelain tiling, enameled surfaces, woodwork, Formica®, vinyl, leather and plastic upholstery, and hard nonporous surfaces made of metal, stainless steel, glazed porcelain, glazed ceramic, fiberglass, stone and plastic.

Kills *Streptococcus pyogenes*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* & *Trichophyton interdigitale* (Athlete's Foot Fungus). \*Virucidal against Influenza Type A, Herpes Simplex Type 2, and HIV-1 (AIDS virus).

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%
<b>INERT INGREDIENTS:</b>	<b>99.82%</b>

**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

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ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 29 2000

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

*(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.

*(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**

Do not store on side. Avoid creasing or impacting of sidewalls.

**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 incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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

**STORAGE AND DISPOSAL**

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

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