47371-155 10/7/2003 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 7, 2003

Mr. Robert J. Sloan Sr. Regulatory Services Associate H & S Chemicals Division c/o Lonza, Inc. 17-17 Route 208 Fair Lawn, NJ 07410

Subject: Formulation RTU-6075A EPA Registration Number 47371-155 Application Dated July 17, 2003 EPA Received Date July21, 2003

Dear Mr. Sloan:

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

Proposed Amendment:

- revised first aid statement
- revised precautionary statements and storage and disposal

General Comments:

- 1. Under Precautionary statements delete the statement "Wash contaminated clothing before reuse." Revise this section to read Caution "Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling".
- 2. Under Directions For Use in the section beginning "Rinse all surfacesdelete "as a disinfectant and Do not use on utensils, replace with the following: glassware, *dishes or appliance interior surfaces*.
- 3. Since this is intended for use in hospitals and related health facitiles, and include the surface "metal beds" the following compared must be included on the label".

SYMBOL		
SURNAME		
DATE		

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"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 sem-critical medical devices prior to sterilization or high level disinfection."

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or

This product is not for use on medical device surfaces.

Refer to PR Notice 94-4 for detailed information.

4. Under Storage and Disposal add "Wrap and discard in trash...."

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy 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 Drusilia Copeland on (703) 308-6224.

Sincere

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

Enclosure Stamped Label

PRECAUTIONARY STATEMENTS HAZARDS TO HUMAN AND DOMESTIC ANIMALS CAUTION. Wash contaminated 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.

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.

PHYSICAL AND CHEMICAL HAZARDS

Flammable. Keep away from heat or open flame.

(For 5 gallon & larger only)

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.

ACCEPTED vith COMMENTS in EPA Letter Dated:

OCT 7 - 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Art as amended, for the pesticide, registered under EPA Reg. No. 47371-155

FORMULATION RTU-6075A

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*VIRUCIDAL

READY TO USE

DISINFECTANT-DEODORANT

Active Ingredients:

n-Alkyl (C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%)	
dimethyl benzyl ammonium chloride	0.13%
n-Alkyl (C ₁₂ 50%, C ₁₄ 30%, C ₁₆ 17%, C ₁₈ 3%)	
dimethyl ethylbenzyl ammonium chloride	0.13%
Inert Ingredients:	99.74%
Total	

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

EPA Reg. No. 47371-155 EPA Est. No. (as indicated on container) Net Contents: (insert container size here)

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

A hard surface disinfectant and space deodorant. It is effective against Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus, and other odorcausing bacteria on environmental surfaces, such as toilet seats, telephones, wash basins, metal beds and springs, trash containers, carts, hampers, lockers, door knobs, and glazed tile.

As a space spray, it is effective in deodorizing locker rooms, meeting rooms, bathrooms and shower rooms, classrooms, closets, laundry chutes, and sick rooms.

For use in schools, colleges, office buildings, hospitals, nursing homes, hotels, motels, gas stations, in motor vehicles and in the household.

*Virucidal against Herpes Simplex type 2.

An effective mildewstat on precleaned hard, nonporous, environmental surfaces.

DIRECTIONS FOR USE

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

Aged or infirmed people should be removed from the room before spraying.

FOR DISINFECTING: Remove gross filth and heavy soil deposits. Preclean all surfaces prior to disinfection. Hold sprayer about 6 to 8 inches from surface and spray until surface is thoroughly wet for a contact time of 10 minutes. No dilution necessary. Let air dry or wipe dry.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

TO DEODORIZE: Use a space spray. Spray upwards toward center of the room. The number of trigger strokes will depend on the size of the room and severity of the odor problem. No dilution necessary.

MILDEWSTATIC INSTRUCTIONS: Will effectively inhibit the growth of mold and mildew plus the odors caused by them when applied to precleaned, hard, nonporous environmental surfaces such as floors and walls. Apply by spraying surfaces until thoroughly wet. Let air dry. Repeat application weekly or more often if growth reappears. (Note to reviewer: If the container size is one gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If container is greater than one gallon, the following storage and disposal statements will be used:) 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 side walls. Open dumping is prohibited.

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

(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

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

FORMULATION RTU-6075A EPA REG. NO. 47371-155 EPA DRAFT LABEL 7-14-03

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