

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

JAN 28 2004

SUBJECT: Formulation RTU-6075  
EPA Registration Number: 47371-137  
Application Dated: October 28, 2003  
Received Date: October 30, 2003

Dear Mr. Sloan:

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

- revise label language
- update to comply with PR Notices

**Conditions**

Revise the label as follows:

1. Revise page two, third section, by specifying that this product is for use on *glazed* tile, which is a hard non porous surface.
2. We have concerns about the use of this product as a space deodorant. Please be aware that at the time of Reregistration the Agency will reconsider the use of this product for the non-pesticidal use as a space spray. You may be asked to remove this use which is not consistent with the pesticidal uses of this product. You are not registered as an air sanitizer.
3. Revise the section on page two beginning: "Rinse all surfaces that..." to end as follows: "Do not use on utensils, glassware, dishes or *appliance interior surfaces* as a disinfectant."

**CONCURRENCES**

| SYMBOL  |  |  |  |  |  |  |  |
|---------|--|--|--|--|--|--|--|
| SURNAME |  |  |  |  |  |  |  |
| DATE    |  |  |  |  |  |  |  |

4. Based on our conversations with representatives from your company on 1/27/04 and 1/28/04 we understand that this product is sold as a pump sprayer in containers up to 1 gallon in size. As this is the case, delete the following text from the label which is not appropriate for this type of container in these sizes:

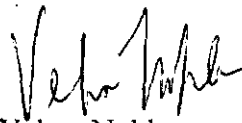
- A. Delete the "Environmental Hazards" statement.
- B. Delete all "Storage and Disposal" instructions for containers greater than one gallon.

**General Comments**

A stamped copy of the accepted labeling 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 concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure: Stamped Label  
7510C:T.Lantz:1/26/04:47371-137

| CONCURRENCES |  |  |  |  |  |  |  |  |
|--------------|--|--|--|--|--|--|--|--|
| SYMBOL       |  |  |  |  |  |  |  |  |
| SURNAME      |  |  |  |  |  |  |  |  |
| DATE         |  |  |  |  |  |  |  |  |

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

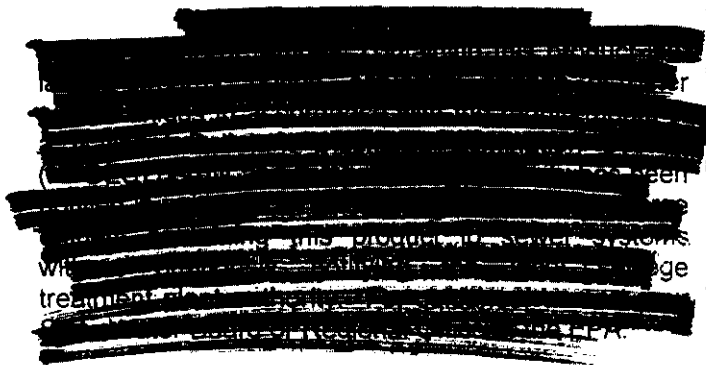
**FIRST AID**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the 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 a Poison Control Center or doctor or going for treatment.

*(Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statements will be used:)*



**FORMULATION RTU-6075**

**READY TO USE**

**Disinfectant – Deodorant - \*Virucidal**

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 .....   | 0.13%   |
| 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 .....  | 0.13%   |
| Other Ingredients:.....   | 99.74%  |
| Total:.....   | 100.00% |

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

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

EPA Reg. No. 47371-137

EPA Est. No. *(insert EPA Establishment number here)*

Net Contents *(insert container size here)*

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
JAN 28 2004

Insecticide,  
Fungicide, and Herbicide Act as  
pesticide,  
Registered under EPA Reg. No. 47371-137

A hard surface disinfectant and space deodorant.

It is effective against Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus and other odor-causing bacteria

Use on hard, nonporous environmental surfaces, such as toilet seats, telephones, wash basins, metal beds and springs, trash containers, carts, hampers, lockers, door knobs and 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, office buildings, hospitals, nursing homes, hotels, motels, colleges and in the household.

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

\*Virucidal against Herpes Simplex 2.

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

**DIRECTIONS FOR USE**

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

**FOR DISINFECTING:** 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.

**TO DEODORIZE:** Use as 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 pre-cleaned, hard, non-porous, inanimate, environmental surfaces such as floors and walls. Apply by spraying surfaces until thoroughly wet. Let air dry. Repeat application weekly or more often if mildew growth reappears.

(Note to reviewer: Only One of the following two statements will 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.

(If container size is 1 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 reuse empty container. Discard in trash or recycle.

(If container size is greater than gallon, the following storage and disposal statements will be used:)

[REDACTED SECTION]