

47371-77

10-9-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 9 2003

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

SUBJECT: Formulation HTA-64
EPA Registration Number: 47371-77
Application Dated: July 11, 2003
Receipt Date: July 14, 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 the "Precautionary Statements" to include the following language: "*Harmful if swallowed.*"
2. Your label includes claims for the product as a "Deodorizer," but does not include directions for this use. Add the following directions for use as a "*Deodorizer: Thoroughly wet surfaces using a solution of 2 ounces per gallon of water. Apply with a mop, sponge, cloth, coarse spray, or by soaking. Allow to air dry.*"

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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."

4. Add the following statements to the directions on page three beginning: "For use as a sanitizer on conveyors..." to end as follows: "When treating conveyors, do not let sanitizer contact food or apply to conveyor when food products or packaging are present."

5. Revise the "Directions for Sanitizing" to include the following:

A. Replace the statement: "Precognize first." with the following as per DIS/TSS 17: "Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment. Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Then, use 2 ounces per..."

B. Add this text immediately after the statement: "Can be applied with a mop, sponge, trigger sprayer or by soaking." "Apply by soaking to dishes, glasses and eating utensils. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray."

6. Add the following text to the directions for "Restaurant and Bar Use" by deleting "wash with detergent, rinse thoroughly and" and replace with: "Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment. Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Immerse in a solution of..."

7. The directions for "Beverage Plants" and "Sanitary Filling" and "Storage Tank Sanitizing" include statements which are not in agreement with PR Notice 2000-5. Revise the "Beverage Plants" to include the following statement: "Allow the solution to remain...at which time the sanitizing solution is to be drained from the system." Revise the "Sanitary Filling" directions to include: "A sanitizing solution of 175 ppm active quat is to be used in the external...". Revise the "Storage Tank Sanitizing" to include: "A solution of 175 ppm quat is to be applied..."

8. In the "Directions for Sanitizing Eating and Drinking Utensils in Eating Establishments" revise #3 to state: "Rinse with potable water."

9. Delete the following phrase from the "Beverage Plants" directions: "after cleaning thoroughly rinse equipment with cold or lukewarm water." then add the following statement to the directions for "Beverage Plants," "Sanitary Filling," and "Storage Tank Sanitizing": "Wash surfaces with compatible detergent and rinse with potable water prior to sanitizing."

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10. Add the following text to the directions for "Storage Tank Sanitizing": "For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray."

11. Revise the one gallon "Storage and Disposal" statement to include the following: "Wrap and discard in trash or recycle."

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:10/9/03:47371-77

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE: Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, safety glasses or face shield), protective clothing and gloves (rubber or chemical resistant) when handling. 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.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

(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.

FORMULATION HTA-64

DISINFECTS - DEODORIZERS - SANITIZES

BACTERICIDAL *VIRUCIDAL FUNGICIDAL

Active Ingredients:

n-Alkyl (C ₁₄ 60%, C ₁₆ 30%, C ₁₈ 5%, C ₁₂ 5%)	
dimethyl benzyl ammonium chloride	1.69%
n-Alkyl (C ₁₂ 68%, C ₁₄ 32%)	
dimethyl ethylbenzyl ammonium chloride	1.69%
Other Ingredients:.....	96.62%
Total:.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-77

EPA Est. No. (insert EPA Est. No. here)

Net Contents (insert container size here)

Manufactured by:
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. **47371-77**

FORMULATION HTA-64

EPA REG. NO. 47371-77

EPA DRAFT LABEL DATED 7-10-03

FISHERIES, MILK, CITRUS, ICE CREAM AND POTATO PROCESSING PLANTS: Applied routinely as a disinfectant on walls and floors will reduce or eliminate odors in the processing area. Use on filling equipment to reduce or eliminate bacteria associated with condensation on equipment and pipes. Follow disinfecting directions.

For use as a sanitizer on conveyors and equipment to reduce or eliminate odors in the processing area. Also, for use on filling equipment to reduce bacteria associated with condensation on equipment and pipes. Follow sanitizing directions.

FOR SANITIZING: For use on hard, nonporous surfaces, such as counter tops, eating utensils and drinking glasses. Preclean first. Then, use 2 ounces per 3 gallons of water, for a minimum contact time of 1 minute, in a single application. Can be applied with a mop, sponge, cloth, or coarse sprayer or by soaking. The use solution is prepared fresh for each use, then discarded. Drain thoroughly. Allow to air dry. Do not rinse.

Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

RESTAURANT AND BAR USE: For use as a sanitizer on dishes, glassware, silverware, cooking utensils, wash with detergent, rinse thoroughly and immerse in solution of 2 oz. per 3 gallons of water for at least 1 minute. Drain thoroughly. Allow to air dry. Do not rinse.

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment; after cleaning thoroughly rinse equipment with cold or lukewarm water. Fill equipment with solution of 2 ounces per 3 gallons of water (175 ppm quat). Allow the solution to remain in contact with equipment for at least 1 minute or until operations resume at which time the sanitizing solution should be drained from the system. Allow to air dry. Do not rinse

To insure the removal of flavors, it is suggested that during changeover between products the system should be cleaned, rinsed and flushed with the sanitizing solution for at least 1 minute. Allow to drain completely and air dry before using. Do not rinse.

SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. The product is to be proportioned into the final rinse water line of the container washer or rinser in a concentration of 175 ppm. A sanitizing solution of 175 ppm active quat should be used in an external application for the filler and closing machine. Follow sanitizing directions.

STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. A solution of 175 ppm quat should be applied manually or used in combination with automated cleaning systems. Drain thoroughly. Do not rinse. For mechanical operations or automated systems, the used sanitizing solution may not be reused for sanitizing, but may be reused for other purposes such as cleaning.

For Wisconsin Use Only

SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS:

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner. (A commercial cleaner or detergent may be recommended.)
3. Rinse with clean water.
4. Sanitize in a solution of 2 fluid ounces per 3 gallons of water (175 ppm quat). Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain-board to air dry. Do not rinse.
6. Fresh sanitizing solution should be prepared at least daily or more often if visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HSS 196.13 of the Wisconsin Administrative Code.

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(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:)

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. Do not reuse empty container.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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

(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 way 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.