

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 17 2003

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

SUBJECT: HS-451 Disinfectant/Sanitizer (50%)  
EPA Registration Number: 47371-161  
Applications Dated: July 17 and July 24, 2003  
Received Dates: July 21 and July 25, 2003

Dear Mr. Sloan:

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

- revise label language
- update to comply with PR Notices

**Conditions**

Revise the label as follows:

1. The Agency has completed risk assessments to characterize the chemical, Alkyl Dimethyl Ammonium Chloride (ADBAC). During this process, the acute toxicology profile was determined for End Use Products (EUP) with an active ingredient concentration ranging from 40% to 80%. According to this data, this product is classified as follows:

Primary Eye	Tox I
Primary Skin	Tox I
Acute Inhalation	Tox II
Acute Oral	Tox II
Acute Dermal	Tox II

Thus revise the Precautionary Statements to read exactly as follows:

CONCURRENCES							
SYMBOL	7510C						
SURNAME	R. Sloan						
DATE	10/16/03						

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"Corrosive. Causes irreversible eye damage and skin burns. *May be fatal if inhaled, swallowed or absorbed through the skin.* Do not get in eyes, on skin, or on clothing. Do not breath vapor. Wear protective eyewear (goggles, safety glasses or face shield), protective clothing and rubber gloves. *Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.* Remove contaminated clothing and wash before reuse."

2. Revise the "First Aid" statements by adding "**If inhaled:** *Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.*"

3. Your product requires child resistant packaging as per 40 CFR part 157.22. Reply to this correspondence by submitting certification that this type of packaging is being used as per 40 CFR part 157.34.

4. Revise the ppm level for use of this product as a disinfect such that it accurately reflects this formulation. Revise both instances on page 2 which refer to this product as a disinfectant at 800 ppm to read **781** ppm.

5. Revise the Disinfection directions by adding the following text immediately after the statement: "The solution can be applied with a mop, sponge, or coarse trigger sprayer or by soaking." "*Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray.*"

6. 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."

7. Revise the directions "For Poultry/Swine house Disinfecting" such that #2 ends as follows: "...occupied or traversed by poultry/swine."

8. Your directions for poultry/swine house disinfecting are incorrect. Change "All treated equipment that will be in contact with feed..." to state the following as per DIS/TSS-18: "*Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent and rinse with potable water before reuse.*"

9. Add the following to the directions "For sanitizing food contact surfaces": Add this text immediately after the statement: "The solution can be applied with a mop, sponge, or cloth as well as by soaking." "*Apply by soaking to dishes, glasses and eating utensils.*"

10. Add the following directions to the "Restaurant and Bar Use" section of the label immediately following "...and cooking utensils." 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-*

CONCURRENCES

SYMBOL							
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DATE							

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clean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Then immerse in solution..." deleting the phrase: "Wash with detergent, rinse thoroughly, and"

11. The directions for "Beverage Plants" and "Sanitary Filling" 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 200 ppm active quat is to be used in the external..."

12. Delete the following phrases from Storage Tank Sanitizing "Wash with detergent, rinse thoroughly, and from the Beverage Plants directions: "clean equipment thoroughly then rinse equipment with cold or lukewarm water." Replace with 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."

13. 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."

14. Delete the statement beginning "When solution becomes visibly dirty..." from the direction For Use in Federally Inspected Meat and Poultry Establishments. Replace with the following statement: "Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted."

15. 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,
[Handwritten Signature]

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

Enclosure: Stamped Label

7510C:T.Lantz:10/16/03:47371-161

CONCURRENCES

Table with 8 columns and 3 rows (SYMBOL, SURNAME, DATE) for tracking concurrences.

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND ANIMALS**

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 protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed. Avoid contamination of food. Remove and 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 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.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

*(For 5 gallon & larger)*

**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.

**HS-451 DISINFECTANT /  
SANITIZER (50%)**

Active Ingredients:

n-Alkyl (C<sub>14</sub> 50%, C<sub>12</sub> 40%, C<sub>16</sub> 10%)  
dimethyl benzyl ammonium chloride..... 50.0%  
Other Ingredients:..... 50.0%  
Total:..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

EPA Reg. No. 47371-161

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

Net Contents *(insert container size here)*

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

**OCT 17 2003**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. **47371-161**

For disinfecting/sanitizing precleaned hard, nonporous surfaces in nursing homes, schools, office buildings, farms, restaurants, bars, beverage plants, and federally inspected meat and poultry establishments.

Effective against the representative gram-positive pathogen *Staphylococcus aureus*, the representative gram-negative pathogen *Salmonella choleraesuis*, and the representative hospital pathogen *Pseudomonas aeruginosa*.

**USES:** Floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, athletic equipment, garbage cans, lavatory fixtures and other hard inanimate nonporous surfaces.

**DISINFECTANT** ..... 1 oz. per 5 gallons  
..... (800 ppm quat)  
**SANITIZER** ..... ¼ oz. per 5 gallons  
..... (200 ppm quat)

**DIRECTIONS FOR USE**

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

**DILUTION INSTRUCTIONS**

For use as a disinfectant at 800 ppm, add 1 ounce (2 tablespoonfuls) in 5 gallons of water.

For sanitizing at 200 ppm, add and stir ¼ ounce (½ tablespoonful) in 5 gallons of water.

**FOR DISINFECTING**

Pre-clean all surfaces prior to disinfection. Then thoroughly wet surfaces with the required dilution. The solution can be applied with a cloth, mop, sponge, or coarse trigger sprayer, or by soaking. Let solution remain on the surface for a minimum of 10 minutes. Wipe dry with a clean cloth or sponge or allow to air 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.

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

Rinsing of floors is not necessary unless the floors are to be waxed or polished.

**FOR POULTRY / SWINE HOUSE DISINFECTING:**

1. Remove all poultry / swine and feeds from premises, trucks, coops and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
8. All treated equipment that will be in contact with feed or drinking water must be rinsed with potable water before using.

**FOR SANITIZING FOOD CONTACT SURFACES**

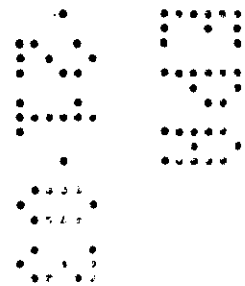
For use on hard nonporous surfaces such as counter tops, eating utensils, and drinking glasses.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Thoroughly wet surfaces with a solution of ¼ ounce product per 5 gallons of water. Let the solution remain on surface for a minimum of 1 minute. The solution can be applied with a mop, sponge or cloth as well as by soaking. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Allow to air dry. Do not rinse.

**RESTAURANT AND BAR USE**

For use as a sanitizer on dishes, glassware, silverware and cooking utensils. Wash with detergent, rinse thoroughly, and immerse in a solution of ¼ ounce product per 5 gallons of water for at least 1 minute. Drain thoroughly. Allow to air dry. Do not rinse.



**STORAGE TANK SANITIZING**

Recommended for sanitizing beer fermentation and holding tanks. Wash with detergent, rinse thoroughly, and use a solution of ¼ ounce product per 5 gallons of water with automated cleaning systems for at least 1 minute. Drain thoroughly. Allow to air dry. 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.

**BEVERAGE PLANTS:** For sanitizing of bottling or pre-mix dispensing equipment, clean equipment thoroughly, then rinse equipment with cold or luke warm water. Fill equipment with solution of ¼ ounce product per 5 gallons of water (200 ppm of 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 before using. Allow to air dry. Do not rinse.

**SANITARY FILLING:** Recommended for use in sanitizing bottles or cans in the final rinse application. To be proportioned into the final rinse water line of the container washer or rinser in concentration of 200 ppm. A sanitizing solution of 200 ppm active quat should be used in an external application for the filler and closing machine. Allow to drain and air dry. Do not rinse.

**FOR USE IN FEDERALLY INSPECTED MEAT AND POULTRY ESTABLISHMENTS** as a sanitizer not requiring a rinse.

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

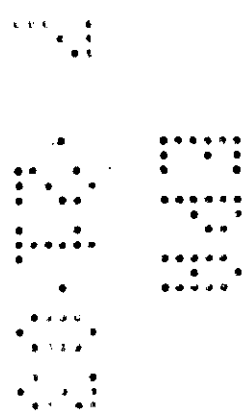
Apply ¼ ounce product (200 ppm active quat) per 5 gallons of water for a 1 minute contact time. Allow to drain and air dry. Do not rinse.

When solution becomes visibly dirty, discard and provide fresh solution.

**TO SANITIZE PREVIOUSLY CLEANED FOOD GRADE EGGS IN SHELL EGG AND EGG PRODUCT PROCESSING PLANTS:**

Spray with ¼ ounce product per 5 gallons of water (200 ppm active quat) for 1 minute. The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be immediately broken for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

**Note:** Only clean, whole eggs can be used for sanitizing. Dirty, cracked or punctured eggs cannot be sanitized.



(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 or persons unfamiliar with its proper use. 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.

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

(Fiber drums with liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(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.

