

47371-161

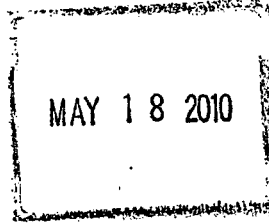
05/18/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Robert Quick
Regulatory Consultant to H & S Chemicals Division
Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, D.C. 20001

Subject: HS-451 Disinfectant/Sanitizer (50%)
EPA Registration No.: 47371-161
Amendment Date: January 20, 2009
EPA Receipt Date: January 28, 2009



Dear Mr. Quick,

The following amendment, submitted in connection with registration under section 3(c)(7)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

Addition of New Use, Additional Food Use

Conditions

Dietary, Residential and Occupational Exposure

Although human dietary exposure to ADBAC residues resulting from use of the preserved sponge on food contact surfaces such as countertops or to wash dishes and eating utensils in the sink is expected to be relatively low, there are no magnitude of the residue studies available to demonstrate this. Therefore, confirmatory data is required to support these assumptions. Depending upon the confirmatory data, the toxicological endpoints may need to be revised to assess dietary exposure risk, particularly the acute dietary endpoint.

1. Provide the Agency with residual or leaching data to validate the conservativeness of the screening assessment and thus generate a more refined assessment. This is to be accomplished by providing a protocol for review and approval prior to data collection. Submit this protocol for review within 120 days of the date of this letter. Submit confirmatory data for review within 180 days of the acceptance of the protocol.

CONCURRENCES

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SURNAME	J. J. [unclear]						
DATE	5/18/10						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

The study protocol must involve behavior similar that of a homeowner, which includes the immersion of a treated sponge in a known volume of water, squeezing the water into a separate container until there is no dripping, and subsequently analyzing this water to determine the level of ADBAC leaching out with each soaking/wringing cycle of the sponge. This is repeated with each sponge to determine the rate of ADBAC loss over time until residues are either non-detectable or have reached a plateau.

2. This label includes PPE restrictions of protective eyewear, protective clothing, and rubber gloves. These PPE restrictions must be included on the label for preservation of wet-packaged sponges.

3. If these conditions including the labeling changes which follow are not complied with, this Registration will be subject to cancellation in accordance with FIFRA section 6 (e).

4. Your release for shipment of this product bearing the revised labeling constitutes acceptance of these conditions.

5. Revise the Precautionary Statements to include: "...Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco or using the toilet. Remove contaminated..."

6. Add the following to the Environmental Hazards statements such that this section will reflect the environmental concerns associated with this active ingredient: "This pesticide is toxic to fish. Do not discharge..."

7. As per PR Notice 2000-5, mandatory statements are required in the directions for use section of the label. As such make the following corrections:

- First section under For Disinfecting: "...Apply with a cloth, mop, sponge, or ..."
- Disinfection Procedures for poultry and swine: "...Saturate surfaces with the disinfecting solution..."
- In the For Sanitizing Food Contact Surfaces: "...Apply with a mop, sponge..."
- Storage Tank Sanitizing: "For sanitizing beer fermentation and holding..." and "For mechanical...the used sanitizing solution is not for reuse as a sanitizer, but may be reused..."
- Beverage Plants: "To insure removal of flavors during change over between products, the system must be cleaned..."
- Sanitary Filling: "Use in sanitizing bottles or cans in the final rinse application..."
- To Preserve Wet-Packed Sponges: "...The use solution is applied by mechanically pouring..." and "...The incorporation rate for the active ingredient..." (deleting the word target).

CONCURRENCES

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8. Add the following statement immediately proceeding #6 in the Poultry and Swine House directions: *“Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.”*

9. Make the following revisions to the Storage and Disposal statements on page eight:

- Delete the following phrase in the fiber drums with liner section as it is not accurate for a liquid product: *“to loosen clinging particles”*.
- Add the following phrase to the fiber drums with liner section: *“...Then offer for recycling if available or dispose of...”*
- You have indicated that your product will only be marketed in containers larger than 5 gallons. As such revise the rinse statement by deleting: *“Agitate vigorously and”* and replacing with: *“Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times.”*

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.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. 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 (7510P)

Enclosures: Stamped Label, DER D361577, D363241, D363243
7510P:T.Lantz:5/17/10:47371-161 sponge new use

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HS-451 DISINFECTANT/SANITIZER (50%)

Active Ingredients:

n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 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.

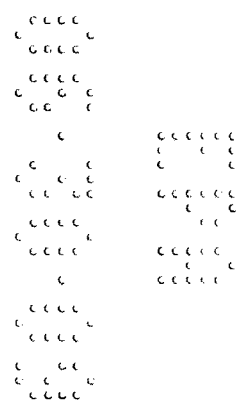
90 Boroline Road

Allendale, NJ 07401

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 18 2010

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



(Note to reviewer: The following is considered optional marketing language.)

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.

For the preservation of wet-packed (cellulose) sponges.

DIRECTIONS FOR USE

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

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

DILUTION INSTRUCTIONS

For use as a disinfectant at 781 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. Spray 6 – 8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. 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, dishes or appliance interior surfaces 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 / swine.
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 all 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. Apply by soaking to dishes, glasses and eating utensils. 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. Remove gross filth 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 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 surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Use a solution of ¼ ounce product per 5 gallons of water with automated cleaning systems for at least 1 minute. 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. 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. Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. 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 is to 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 is to 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. Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. 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 is to 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.

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

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.

(Note to Reviewer: The preservation of wet-packaged sponges use will only be used by itself on a commercial label. None of the other uses that are on the HS-451 Disinfectant/Sanitizer (50%) Master Label will be included).

TO PRESERVE WET-PACKED SPONGES (Industrial Use Only)

HS-451 Disinfectant/Sanitizer (50%) can be used to preserve wet-packed sponges only at the point of manufacture of the sponge.

Sponges must be treated with HS-451 Disinfectant/Sanitizer (50%) in an automated system that is designed to prevent dermal and inhalation exposure to workers. Thoroughly wet uncut sponge material with a use-solution of HS-451 Disinfectant/Sanitizer (50%) at a dosing rate of 0.38 – 1.15 ounces of HS-451 Disinfectant/Sanitizer (50%) per gallon of water. The use-solution can be applied by mechanically pouring, drizzling, immersion or by use of a low volume very coarse spray. Mechanically squeeze excess solution from the sponge, leaving the sponge material damp but not dripping. The target incorporation rate for the active ingredient (alkyl dimethyl benzyl ammonium chloride or ADBAC) in the finished sponge is 900-1500 ppm. Mechanically cut sponges to the desired size and seal into polyethylene bags. Do not contact the wet or damp sponges.

Recycle the solution squeezed from the wet sponges into the preservation solution. Prepare a fresh preservation solution as needed.

Wet packed sponge packaging must state "Rinse thoroughly before use (using)".

Sponges may be used on food contact surfaces.

(Note to reviewer: For non-refillable Containers for commercial, industrial and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.)

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. Store in original container in areas inaccessible to children.

Pesticide Disposal:

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

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic and Metal Containers:) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.

(For metal containers only:) DO NOT cut or weld metal containers.

(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.