

47371-54

03-12-2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/8

Ms. Joanna Holcombe
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

MAR 2 2010

SUBJECT: Formulation HS210-37
EPA Registration Number: 47371-54
Application Date: December 11, 2009
Receipt Date: December 15, 2009

Dear Ms. Joanna Holcombe:

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

1) Revise the Precautionary Statements to be in agreement with the Label Review Manual as follows. Correct this section to begin: "**DANGER**. Corrosive. Causes irreversible..." Also revise to include: "... Wash thoroughly with soap and water after handling *and before eating, drinking, using tobacco or using the toilet*. Remove contaminated..."

2) The Precautionary Statements indicate that there is an inhalation hazard associated with this product. As such add the following statements to the First Aid section:
"If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice."

3) 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..."

CONCURRENCES							
SYMBOL	7510P						
SURNAME	J. Jones						
DATE	2/28/2010						

4) Information pertaining to the specific rates at which the product is used is part of the Directions for Use. The fourth section on page three belongs in the Directions for Use section of the label. Place the section beginning: "Disinfectant: 1:700..... Sanitizer: 1:2500" and ending: "...1 oz. per 19 1/2 gallons 150 ppm quat)" in the Directions for Use section.

5) 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 General Use Directions for Disinfecting: "...Apply with a mop, sponge, or cloth...The *use solution* is prepared fresh for..."
- Sanitizing Shell Eggs Intended for Food: "...The solution *must* be warmer than the eggs...Eggs *must* be reasonably dry...The solution *must* not be reused for..."
- Beverage Plants: "To insure removal of flavors *during change* over between products, the system *must* be cleaned..."
- Storage Tank Sanitizing: "...A solution of 1 ounce per 19 1/2 gallons of water (150 ppm quat) *is* applied..."

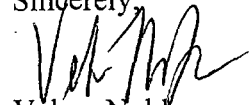
6) Add the following statement as item #3 in the Disinfection section of the Poultry and Swine House directions: "*Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.*"

7) Revise the Fiber drums with liners section on page 6 to be in agreement with 40 CFR 156.140 (a) (3), PR Notice 2007-4 and PR Notice 83-3 as follows: "...Then offer for recycling if available or dispose of liner in a...or by incineration or if allowed by state and local authorities by burning. *If burned, stay out of smoke.* If drum is..."

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 (7510P)

CONCURRENCES							
SYMBOL	7510P:T.Lantz:2/28/10:47	71-54 amendment					
SURNAME							
DATE							

3/8

Formulation HS210-37

Farm Disinfectant / Sanitizer

Active Ingredient:
 Didecyl dimethyl ammonium chloride 37.5%
 Other Ingredients:..... 62.5%
 Total:..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-54
 EPA Est. No. *(insert EPA Est. No. here)*
 Net Contents: *(insert container size here)*
 [Country of origin (insert country)]
 [Manufactured in (insert country)]
 [Barcode]

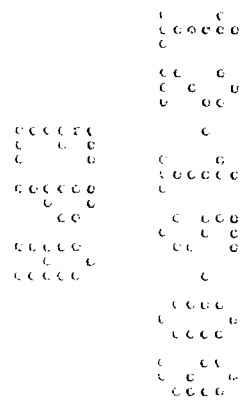
MANUFACTURED BY:
 H&S CHEMICALS DIVISION
 c/o LONZA INC.
 90 Boroline Road
 Allendale, NJ 07401

ACCEPTED
 with COMMENTS
 in Field Office

3/2/10

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended for the pesticides
 registered under EPA Reg. No.

47371-54



Bactericidal in the presence of 5% organic serum, according to current AOAC Use-dilution Test. Effective as a sanitizer, in the presence of 1,000 ppm water hardness, according to AOAC Germicidal and Detergent Sanitizer Test.

For use in hospitals, nursing homes, dairy farms, equine farms, hog farms, poultry and turkey farms, tack shops, kennels, pet shops, veterinary clinics, animal life science laboratories, restaurants and bars, beverage plants, federally inspected meat and poultry processing plants, egg processing plants and, households.

For use on hard, nonporous surfaces such as floors, walls, metal surfaces, glazed porcelain and plastic surfaces (such as polypropylene, polystyrene).

- DISINFECTANT:** 1:700 1 oz per 5 ½ gallons
..... (535 ppm quat)
- SANITIZER:** 1:2500 1 oz. per 19 ½ gallons
..... 150 ppm quat)

ACCEPTED
with COMMENTS
in EPA Label Draft:

MAR 12 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, and Executive Order 12875, registered under EPA Reg. No. 47371-54

DIRECTIONS FOR USE

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

GENERAL USE DIRECTIONS FOR DISINFECTING

Remove gross filth and heavy soil deposits then, thoroughly wet surfaces with a solution of 1 ounce per 5 ½ gallons water for a minimum contact time of 10 minutes. Can be applied with a mop, sponge, or cloth, as well as with a coarse sprayer or soaking. Wipe dry with a clean cloth or sponge or allow to air dry. The recommended use solution is prepared fresh for each use then discarded.

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.

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

(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.

FOR POULTRY AND SWINE HOUSE DISINFECTING

Prior to disinfection:

- All animals, as well as feeds, must be removed from the premises. This includes emptying all troughs, racks, and other feeding and water appliances.
- Remove all litter and droppings from floors, walls, and other surfaces occupied or traversed by animals.
- Thoroughly clean all surfaces with detergent and rinse with water.

Disinfection procedures:

- Thoroughly mix 1 ounce of the concentrate per 5 ½ gallons of water.
- Saturate surfaces above the floor with the disinfectant solution for a period of 10 minutes. Follow standard pattern with overlapping sections so that all surfaces are wet, including rafters, beams, feed troughs, windows, ceiling, etc. Surfaces should be wet to point of run off.
- Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
- All treated equipment that will be in contact with feed or drinking water must be rinsed with potable water before using.

FOR WISCONSIN 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.
3. Rinse with potable water.
4. Sanitize in a solution of 1 fluid ounce per 19 1/2 gallons of water (150 ppm quat). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air-dry.
6. Prepare a fresh sanitizing solution at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference:CFR 180.940 (a)).

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment, after cleaning thoroughly rinse equipment with cold or luke warm water. Fill equipment with solution of 1 ounce per 19 1/2 gallons of water (150 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 must be drained from the system and air dry. Do not rinse.

To insure the removal of flavors, it is suggested that during change over between products, the system should be cleaned, rinsed and flushed with the sanitizing solution for 1 minute.

SANITARY FILLING: To sanitize bottle or cans in the final rinse application, proportion 1 ounce per 19 1/2 gallons of water (150ppm) into the final rinse water line of the container washer or rinser and for the filler and closing machine. Allow the solution to remain in contact with equipment for at least 1 minute, then air dry. Do not rinse.

STORAGE TANK SANITIZING: To sanitize beer fermentation and holding tanks. A solution of 1 ounce per 19 1/2 gallons of water (150 ppm quat) should be applied by coarse spray or used in combination with automated cleaning systems. 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. Allow the solution to remain in contact with equipment 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 2 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-54

