47371-54

D3-D2-2010 UN-STATES ENVIRONMENTAL PROTECT AGENCY

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

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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..."

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UN STATES ENVIRONMENTAL PROTECT AGENCY

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 ½ 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 that 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 ½ 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.

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Product Manager (31) Regulatory Management Branch I Antimicrobials Division (7510P)

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Farm Disinfectant / Sanitizer

Active Ingredient:	
Didecyl dimethyl ammonium chloride	
Other Ingredients:	<u>62.5%</u>
Total:	

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

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Harmful if swallowed or inhaled. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses) and protective clothing and waterproof gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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

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

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.

PHYSICAL AND CHEMICAL HAZARDS

Do not store near heat or open flame.

	ACCEPTED with COMMENTS in EPA Letter Dated: WAR -12 2010 Under the Federal Local Control Fungicide, and Rodentiade Act as amended, for the pesticide, registered under EPA Reg. No. 47371-594	ίς τις ίς τις ίς το ίς το το το το το το το το το το
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FORMULATION HS210-37 EPA REG. NO. 47371-54 EPA STAMPED LABEL10-9-03, DRAFT 12-11-09 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). ACCEPTED

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DISINFECTANT: 1:700 1 oz per 5 1/2 gallons SANITIZER: 1.2500 1 oz. per 19 ½ gallons

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:

- 1. All animals, as well as feeds, must be removed from the premises. This includes emptying all troughs, racks, and other feeding and water appliances.
- 2. 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. 3.

Disinfection procedures:

- 1. Thoroughly mix 1 ounce of the concentrate per 5 $\frac{1}{2}$ gallons of water.
- 2. 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. ccccc
- 3. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment Četeče has been absorbed, set or dried. 000000
- All treated equipment that will be in contact with feed or drinking water must be rinsed with potable water before 4. ς ι ι «ι υ using. CCCCC. ucece

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VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1 oz. of **FORMULATION HS210-37** per 5½ gallons of water (*or equivalent dilution*) for a period of 10 minutes. Wipe or allow to air dry. 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. Thoroughly scrub all surfaces that come in contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 1 oz. of **FORMULATION HS210-37** per 5½ gallons of water (*or equivalent dilution*) for a period of 10 minutes. 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. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse

SANITIZING DAIRY, MEAT AND POULTRY PROCESSING UTENSILS AND EQUIPMENT

For use as a sanitizer on hard, nonporous surfaces, dilute 1 oz. per 19 1/2 gallons of water to provide 150 ppm active quat. Prior to sanitizing, thoroughly clean all surfaces with detergent and rinse with water. The solution can be applied with a mop, sponge, or cloth, as well as spraying or soaking. Saturate or immerse in sanitizing solution for a minimum contact time of 1 minute. Allow the surface to completely drain and air dry before use. Do not rinse. A fresh solution should be prepared at least daily or more often if the solution becomes diluted or soiled.

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.

SANITIZING SHELL EGGS INTENDED FOR FOOD

To sanitize previously cleaned, food-grade eggs, in shell egg and egg product processing plants, (saturate with) (spray with) a solution of 1 oz. in 19 1/2 gallons of warm water (150 ppm quat). The solution should be 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 broken immediately for use in the manufacture of egg products. Eggs should be reasonably dry before casing or breaking. The solution should not be reused for sanitizing eggs.

RESTAURANT AND BAR USE: For use as a sanitizer on dishes, glassware, silverware, 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. If merse in a solution of 1 oz. per 19 1/2 gallons of water (150 ppm quat) for at least 1 minute. Allow to drain and air dry.

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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 guat). 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 ½ 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.

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(Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes - No Reuse Rinsate Statement for Public Health Use products)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **Pesticide Storage:** 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.)

(For Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

(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.

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