

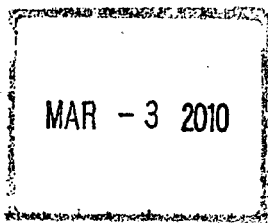
47371-53

3/3/2010

1 of 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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



SUBJECT: Formulation HS210-15
EPA Registration Number: 47371-53
Application Date: December 10, 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. Revise to include: "... Wash thoroughly with soap and water after handling *and before eating, drinking, using tobacco or using the toilet.* Remove contaminated..."
- 2) 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...*"
- 3) 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..."
 - Disinfection Procedures for poultry and swine: "... Saturate surfaces with the disinfecting solution..."
 - Sanitizing Dairy, Meat and Poultry Processing Utensils and Equipment: "... Do not rinse. *Prepare a fresh solution* at least..."

CONCURRENCES							
SYMBOL	B510P						
SURNAME	J. Jones						
DATE	3/3/2010						

- 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..."
- Sanitary Filling: "*Use* in sanitizing bottles or cans in the final rinse application..."
- Storage Tank Sanitizing: "For sanitizing beer fermentation and holding tanks a solution of 150 ppm *is* applied..."


4) 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.*"

5) Revise the Fiber drums with liners section on page 4 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:3/3/10:47371-53 amendment						
SURNAME							
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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER Corrosive. Causes irreversible eye damage. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, face shield, or safety glasses, protective clothing and protective gloves (rubber or chemical resistant). 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.

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

(If container size is 5 gallons or larger, use the following Environmental Hazards statement.)

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

Is a cationic germicide. Do not mix with soap or anionic materials.

FORMULATION HS210-15

FARM DISINFECTANT / SANITIZER

Active Ingredient:
Didecyl dimethyl ammonium chloride 15.0%
Other Ingredients:..... 85.0%
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. 47371-53
EPA Est. No. (as indicated on container)
Net Contents: (insert container size here)
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR - 3 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **47371-53**

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Effective against Pseudomonas aeruginosa, Salmonella enterica and Staphylococcus aureus, in the presence of 5% organic serum, according to current AOAC Use-dilution Tests. 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 and egg processing plants.

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

DISINFECTANT: 1:288 ...2 oz per 4 1/2 gallons water
SANITIZER: 1:992 ...2 oz. per 15 1/2 gallons of water

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 2 oz. per 4 1/2 gallons water for a minimum contact time of 10 minutes in a single application. ~~Can be~~ applied with a mop, sponge, or cloth, as well with a coarse sprayer or by 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 dishes or appliance interior surfaces 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 pre-clean 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.
3. Thoroughly clean all surfaces with detergent and rinse with water.

Disinfection Procedures:

1. Fill tank half way with water. Add required amount (2 oz. per 4 1/2 gallons of water). Mix thoroughly. Fill tank with water.
2. Spray all surfaces above the floor with the disinfectant solution. 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.
3. Saturate surfaces with the ~~recommended~~ disinfecting solution for a period of 10 minutes.
4. Ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
5. All treated equipment that will be in contact with feed or drinking water must be rinsed with potable water before using.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR - 3 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No 47371-53

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