

47371-164

05/14/2004

1/9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Robert Sloan
Sr. Regulatory Services Associate
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

MAY 14 2004

SUBJECT: Formulation HS-1210 Disinfectant/Sanitizer (50%)
EPA Registration Number: 47371-164
Application Dated: November 14, 2003
Receipt Date: November 17, 2003

Dear Mr. Robert Sloan:

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

- add public health pests

Data Matrix

The following correction has been made to the End-Use Data Matrix submitted in conjunction with this amendment: added a reference to the "Disinfectant" testing MRID# 41610801. Make this same addition to the matrix in your files. In addition, you have identified an MRID for *Listeria Monocytogenes* which is incorrect. MRID 46070301 is a study performed on *Vibrio Cholerae*.

Efficacy Data

Acceptable Studies

Data Requirement	Means of Support	Status
<i>Escherichia coli</i> O157:H7 food contact sanitizing	Submitted study, MRID 46070304	Acceptable @ 200 ppm AI in 500 ppm hard water for 1 minute
<i>Shigella sonnei</i> food contact sanitizing	Submitted studies, MRIDs 46070302, 45839403	Acceptable @ 200 ppm AI in 500 ppm hard water for 1 minute
<i>Yersinia enterocolitica</i> food contact sanitizing	Submitted studies, MRIDs 46070303, 45839405	Acceptable @ 200 ppm AI in 500 ppm hard water for 1 minute

CONCURRENCES

SYMBOL	7510C						
SURNAME	J. J. J.						
DATE	5/14/04						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Unacceptable Studies

The claim for effectiveness of this product against *Vibrio cholerae* as a sanitizing rinse is unacceptable. The submitted data supports the use of Letheen Broth as a neutralizer when tested against *Vibrio cholerae*, not the effectiveness of this product against *Vibrio cholerae*. This study must include purity and sterility controls.

The claim for effectiveness of this product against *Listeria monocytogenes* as a sanitizing rinse is unacceptable. You have not addressed the deficiencies regarding the toxicity of the neutralizer to *Listeria monocytogenes* and the effectiveness of the neutralizer.

Delete the claims for *Vibrio cholerae* and *Listeria monocytogenes* from the food contact sanitizing section of the label.

Should you decide to submit additional data in support of these two organisms, specify in your cover letter to the Agency that you are replying to this Agency letter and reference the above date.

Conditions

Revise the label as follows:

A. Make the following revision to page one:

Revise such that the "IF INHALED" heading is in bold text.

B. Make the following revisions to page three:

1. Delete the claims for *Vibrio cholerae* and *Listeria monocytogenes* from the sanitizing food contact surfaces section.

2. The two sets of organisms in the sanitizing food contact surfaces section of the label were tested at different ppm active ingredient. Thus revise to state:

"Modified in the presence of 800 ppm water hardness (calculated as CaCO₃) and **150 ppm active quat**: *Escherichia coli* and *Staphylococcus aureus*"

and

"Modified in the presence of 500 ppm water hardness (calculated as CaCO₃) and **200 ppm active quat...**" against the remaining organisms as many of these additional organisms were only tested in 200 ppm active quat.

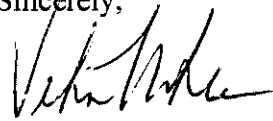
CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

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 (7510C)

Enclosure: Stamped Label
7510C:T.Lantz:5/14/04:47371-164e

419

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed or absorbed through the skin. May be fatal if inhaled. Do not breathe vapor or spray mist. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), 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 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.

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 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.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply in marine and/or estuarine oil fields.

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

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/CHEMICAL HAZARDS

This pesticide is a cationic germicide. Do not mix with soap or anionic materials. Do not use or store near heat or flame.

FORMULATION HS-1210 DISINFECTANT / SANITIZER (50%)

ONE-STEP DISINFECTANT

SANITIZER - GERMICIDE - DEODORANT

Salmonellacidal	Bactericidal	Pseudomonacidal
Staphylocidal	Fungicidal	*Virucidal

Active Ingredients:

Didecyl dimethyl ammonium chloride.....30.00%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)

dimethyl benzyl ammonium chloride.....20.00%

Inert Ingredients:50.00%

Total.....100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No.47371-164

EPA Est. No. (as indicated on container)

Net Contents: (as indicated on container)

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

ACCEPTED
with **COMMENTS** ,
in EPA Letter Dated: 

MAY 14 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-164

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

A concentrated, multi-purpose germicide and deodorant effective in a moderate amount of organic soil (5% serum) according to the AOAC Use-dilution Test.

Disinfects and deodorizes hard nonporous surfaces in one labor saving step.

Use in hospitals, nursing homes, medical clinics, dental offices, schools, colleges, office buildings, hotels and motels, airports, restaurants, bars, beverage plants, citrus plants, breweries, federally inspected meat and poultry plants, veterinary clinics and animal life science laboratories, tack shops, pet shops, breeding and grooming establishments, kennels, poultry and turkey farms, equine farms, dairy farms and hog farms.

Use on hard, nonporous surfaces such as floors, walls, lavatory fixtures, showers, machinery and equipment, garbage cans, metal, stainless steel, glazed porcelain, painted and plastic surfaces.

Bactericidal at 1:1000 dilution (2 oz. per 15½ gallons of water) against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* according to the AOAC Use-Dilution Test method, modified in the presence of 5% organic serum. (See reference sheet for complete list of pathogenic organisms).

DISINFECTANT (1:1000)2 oz. per 15½ gallons of water
..... (500 ppm)
SANITIZER (1:3333)1 oz. per 26 gallons of water
..... (150 ppm)
SANITIZER (1:2496)1 oz. per 19½ gallons of water
..... (200 ppm)

DIRECTIONS FOR USE

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

DISINFECTION / DEODORIZING DIRECTIONS:

If surfaces are visibly dirty, preclean prior to disinfection / deodorizing activity. Prepare a solution of 2 oz. of product per 15½ gallons of water. Apply use-solution with a cloth, sponge, mop, coarse trigger sprayer, or by soaking to thoroughly wet all surfaces. 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. Let solution remain on the surface for a minimum contact time of 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. The use solution is prepared fresh for each use then discarded. Rinsing of floors is not necessary unless they are to be waxed or polished. Food contact surfaces must be thoroughly rinsed with potable water.

(Note to reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must 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 to be used on medical device surfaces.

VIRUCIDAL DIRECTIONS*:

Virucidal against Bovine rhinotracheitis, Avian Infectious Bronchitis virus, and Newcastle Disease virus, Marek's Disease Virus and Infectious Bronchitis Virus – Arkansas strain (IBV) according to the virucidal qualification, modified in the presence of 5% organic serum at a 1:1000 dilution. Follow Disinfection Directions.

FUNGICIDAL DIRECTIONS:

Fungicidal against Trichophyton mentagrophytes (and Candida albicans and Aspergillus glaucus) according to the AOAC fungicidal test, modified in the presence of 5% organic serum at a 1:1000 dilution. For fungicidal activity use in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities. Follow Disinfection Directions.

MOLD AND MILDEW CONTROL DIRECTIONS: To control mold and mildew on hard, nonporous surfaces wash visible soil from the surface. Then apply a use-solution of 2 fluid oz. per 15½ gallons with a mop, sponge, cloth, or coarse trigger sprayer so as to wet all surfaces thoroughly. Let air dry. Repeat application every 7 days to control recurrence of growth.

FISHERY, MILK, CITRUS, ICE CREAM & POTATO PROCESSING PLANTS DISINFECTION DIRECTIONS:

Applied routinely as a disinfectant on walls and floors will reduce or eliminate odors in the processing area. Use on filling equipment to reduce or eliminate odors in the processing area and bacteria associated with condensation on equipment and pipes. Follow Disinfection Directions.

FOR SANITIZING FOOD CONTACT SURFACES:

Effective against the following according to the AOAC Germicidal & Detergent Sanitizer Test

- modified in the presence of 800 ppm water hardness (calculated as CaCO_3):
Escherichia coli
Staphylococcus aureus
- modified in the presence of 500 ppm water hardness (calculated as CaCO_3) against:
Campylobacter jejuni
Escherichia coli (E. coli)
Escherichia coli 0157:H7 (pathogenic E. coli)
Listeria monocytogenes
Salmonella choleraesuis
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

For use on precleaned, hard, nonporous food contact surfaces including plastic and other hard nonporous cutting boards and chopping blocks, counter tops, tables, cooking and eating utensils and drinking glasses. For heavily soiled areas, remove gross food particles by preflush, prescrape and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then rinse with potable water prior to application of sanitizing solution.

Use 1 oz. per 19½ - 26 gallons of water (200 - 150 ppm quat) for a minimum contact time of 1 minute in a single application.

Can be applied with a cloth, sponge, mop, coarse trigger sprayer, or by soaking. Eating utensils and drinking glasses must be sanitized by immersion. Thoroughly wet all surfaces. Drain thoroughly and air dry. Do not rinse.

Fresh sanitizing solution must be prepared at least daily or more often if the use solution becomes diluted. For mechanical applications, use solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

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

RESTAURANT AND BAR USE: For use as a sanitizer on dishes, glassware, silverware and eating and cooking utensils. For heavily soiled areas, remove gross food particles by preflush, prescrape and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then rinse with potable water prior to application of this product. Then immerse in a solution of 1 oz. per 19½ - 26 gallons of water (200- 150 ppm quat) for at least 1 minute. Drain thoroughly and air dry. Do not rinse.

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment, after cleaning thoroughly rinse equipment with cold or lukewarm water. Fill equipment with solution of 1 oz. per 19½ - 26 gallons of water (200 - 150 ppm 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. 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. Do not rinse.

SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. The product is to be proportioned into the final rinse water line of the container washer or rinser in concentration of 150-200 ppm active quat. A sanitizing solution of 150 - 200 ppm active quat should be used in an external application for the filler and closing machine. Do not rinse.

STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. A solution of 150 - 200 ppm active quat should be applied manually or used in combination with automated cleaning systems. Follow directions for sanitizing food contact surfaces. Drain thoroughly. 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.

FOR SANITIZING IN FISHERIES, MILK, CITRUS, POTATO & ICE CREAM PROCESSING PLANTS: For use as a sanitizer on conveyors and equipment to reduce or eliminate odors in the processing area. Also, for use on filling equipment to reduce bacteria associated with condensation on equipment and pipes. Follow directions for sanitizing food contact surfaces.

**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 oz. per 19½ - 26 gallons of water. Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary codes.
- 5) Place sanitized utensils on a rack or drain-board to air dry.
- 6) Prepare 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 196.13 of the Wisconsin Administrative Code.

POULTRY & TURKEY HOUSE DISINFECTANT DIRECTIONS:

Dilution: 1:1000 2 ounces per 15½ gallons of water

1. Remove all poultry 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 water 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.

FARM PREMISE DISINFECTANT DIRECTIONS:

For use in Equine, Dairy and Hog farms

1. Remove all animals and feed from premises, vehicles, and enclosures.
2. 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.
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 all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. 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. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

CITRUS CANKER DISEASE CONTROL

For prevention of Citrus Canker Disease through treatment of equipment. Effective against *Xanthomonas axonopodis* pv. citri (Citrus Canker Disease) at 2000 ppm active quat. Treatments can be applied to trucks, attached trailers, and field equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other hard nonporous equipment taken into infested areas.

Saturate surfaces with a 1:250 use-dilution (5 oz. per 9½ gallons of water or equivalent dilution) (2000 ppm active quat) for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Thoroughly rinse or launder clothing before reuse. Rinse footwear before reuse.

VETERINARY CLINICS / ANIMAL LIFE SCIENCE LABORATORY / PET SHOP / KENNELS / BREEDING AND GROOMING ESTABLISHMENT / TACK SHOP DISINFECTION DIRECTIONS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 oz. of product per 15½ 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 and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment that dispenses food or water with soap or detergent and rinse with potable water before reuse.

(REFERENCE SHEET FOR COMPLETE LIST OF PATHOGENIC ORGANISMS)

BACTERICIDAL AGAINST:

Effective against the following according to the AOAC Use-Dilution Test, modified in the presence of 5% organic serum.

Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella choleraesuis

Enterobacter aerogenes
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Proteus mirabilis
Salmonella typhi
Serratia marcescens
Shigella flexneri
Staphylococcus aureus phage 80
Staphylococcus aureus phage 81
Streptococcus pyogenes

VIRUCIDAL AGAINST*:

Effective against the following according to the virucidal qualifications modified in the presence of 5% organic serum.

Avian Infectious Bronchitis virus
 Bovine rhinotracheitis virus
 Newcastle virus
 Marek's Disease Virus
 Infectious Bronchitis Virus, Arkansas strain (IBV)

FUNGICIDAL & MILDEWCIDAL AGAINST:

Effective against the following according to the AOAC Use-Dilution Test, modified in the presence of 5% organic serum.

Aspergillus glaucus
Candida albicans
Trichophyton mentagrophytes

(If container size is one gallon or less, use the following Storage and Disposal statements):

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Wrap and discard in trash or recycle.

(If container size is greater than one gallon, use the following Storage and Disposal statements):

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Open dumping is prohibited. Do not reuse empty container.

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

(Plastic Containers): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or, if allowed by state and local authorities, by burning. 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.