

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 28 2004

Mr. Robert Sloan
Sr. Regulatory Services Associate
H&S Chemicals Division c/o Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: Formulation HS-3328
EPA Registration No. 47371-104
Application Date: 11/26/03
Receipt Date: 12/1/03

Dear Mr. Sloan:

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

Addition of claims against two organisms

EFFICACY

See the attachment for efficacy comments

GENERAL COMMENTS

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL	7510C						
SURNAME	Z. Jones						
DATE							

HIGHLIGHTED
COPY

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE: Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield), protective clothing and protective gloves (rubber or chemical resistant) when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before use.

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.

(Note to reviewer: If the 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.

Formulation HS-3328

DISINFECTANT-SANITIZER-DEODORIZER

Active Ingredients:

n-Alkyl (C ₁₄ , 60%; C ₁₆ , 30%; C ₁₈ , 5%; C ₁₂ , 5%)	
dimethyl benzyl ammonium chloride	7.04%
n-Alkyl (C ₁₂ , 68%; C ₁₄ , 32%)	
dimethyl ethylbenzyl ammonium chloride	7.04%
Other Ingredients:	85.92%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

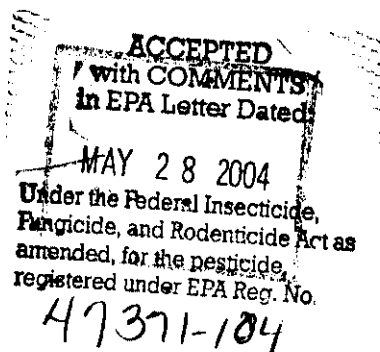
See [side] [back] [left] [right] panel for Precautionary Statements and First Aid

EPA Reg. No. 47371-104

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 07410



An effective, multi-purpose disinfectant - Staphylocidal, Pseudomonacidal and Salmonellacidal on nonporous, inanimate surfaces.

Formulation HS-3328 is an effective sanitizer for use on food contact surfaces; it also fulfills the criteria of *Appendix F, of the Grade "A" Pasteurized Milk Ordinance 2002*, recommendation of the *U.S. Public Health Service*, in hard waters up to [500] [750] ppm hardness (calculated CaCO_3).

Formulation HS-3328 at 1 oz. per 5 1/2 gallons of water [alternate: 0.18 oz. per gallon of water, or 3.64 fl. oz. per 20 gallons of water, or equivalent dilution] is an effective sanitizer for use on food contact surfaces in 60 seconds at 200 ppm active and 750 ppm hard water against:

Escherichia coli
Staphylococcus aureus

Formulation HS-3328 at 1 oz. per 6 1/4 gallons of water [alternate: 0.16 oz. per gallon of water, or 3.19 fl. oz. per 20 gallons of water] [or equivalent dilution] is an effective sanitizer for use on food contact surfaces in 60 seconds at 175 ppm active and 500 ppm hard water against:

Escherichia coli
Staphylococcus aureus

DISINFECTANT 1:256	(550 ppm active quat)
SANITIZER 1:640	(220 ppm active quat)
SANITIZER 1:704	(200 ppm active quat)
SANITIZER 1:821	(175 ppm active quat)

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 28 2004
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
47371-104

DIRECTIONS FOR USE

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

DIRECTIONS FOR DISINFECTING: For use in hospitals and nursing homes, federally inspected meat and poultry plants, restaurants and bars, beverage plants, barber shops, schools and colleges.

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

Remove gross filth and heavy soils. Pre-clean all surfaces then thoroughly wet surfaces with Formulation HS-3328. Use 1/2 oz. per gallon of water for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. The recommended use solution is prepared fresh for each use, then discarded. Rinsing is not necessary, unless floors are to be waxed or polished.

Rinse food contact surfaces such as counter tops, tables, picnic tables, appliances and / or stove tops with potable water prior to reuse. Do not use on glasses, dishes or utensils as a disinfectant.

DISINFECTION OF BARBER TOOLS: Barber tools (such as combs, brushes, razors and scissors) can be disinfected by immersing in a 1/2 oz. per gallon solution for a minimum of 10 minutes.

(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.

(Note to reviewer: On a final printed label, only one of the two dilution rates below will be used in the sanitizing direction sections):

"[1 oz. per 5 [- 5 ½] gallons (0.18 [- 0.20] oz. per gallon) (3.64 [- 4.00] fl. oz. per 20 gallons) of water (or equivalent dilution) (200 [- 220] ppm active quat)]"

or

"[1 oz. per 5 - 6 ¼ gallons (0.16 - 0.20 oz. per gallon) (3.19 - 4.00 fl. oz. per 20 gallons) of water (or equivalent dilution) (175 - 220 ppm active quat)]"

DIRECTIONS FOR SANITIZING: For use on hard, nonporous surfaces such as eating utensils and drinking glasses.

Remove gross particles and soil by a pre-flush, pre-scrub, 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, use [insert appropriate dilution rate here from box] for a minimum contact time of 1 minute in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. Apply by soaking to dishes, glasses and eating utensils. 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. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Do not rinse.

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, cooking utensils, Remove gross particles and soil by a pre-flush, pre-scrub, 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. Immerse in a solution of [insert appropriate dilution rate here from box] for at least 1 minute. Do not rinse. Allow to air Dry. Prepare a fresh solution at least daily or when use solution becomes visibly dirty.

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Fill equipment with solution of [insert appropriate dilution rate here from box]. 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 change over between products, the system should be cleaned, rinsed, and flushed with the sanitizing solution for 1 minute. Allow to drain completely before using.

SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Formulation HS-3328 is to be proportioned into the final rinse water line of the container washer or rinser in concentration of [175 - 220] [200 [- 220]] ppm. A sanitizing solution of [175 - 220] [200 [- 220]] ppm active quat should be used for the filler and closing machine.

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STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. A solution of [175 - 220] [200 [- 220]] ppm should be applied by spraying 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. 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.

DIRECTIONS FOR SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS:

- 1) Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment.
- 2) Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and
- 3) Rinse with potable water prior to sanitizing.
- 4) Immerse in a solution of [insert appropriate dilution rate here from box]. Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary code.
- 5) Place sanitized utensils on a rack or drainboard to air dry.
- 6) Prepare a fresh solution at least daily or when use solution becomes visibly dirty.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HSS 196.13 of the Wisconsin Administrative Code.

(Note to reviewer: If the container size is one gallon or less, the following Storage & Disposal statements will be used:)

STORAGE AND DISPOSAL

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

(Note to reviewer: If the container size is greater than one gallon, the following Storage & Disposal statements will be used:)

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.

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 incinerate, or if allowed by state and local authorities, burn. 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.

