

47371-32

01-12-2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Patti Phillips,
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401, USA

Attention Mrs. Phillips.

JAN 12 2012

Subject: Formulation HS-8451P
Registration No.: 47371-32
Amendment Dated: October 25, 2011
Receipt Date: October 25, 2011
Submission #: 905963

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

Proposed Amendment

- Add optional non-FIFRA DOT symbol placeholder;
- Add the optional Spanish word for Danger [PELIGRO];
- Add Note to reviewer (page 2);
- Add the storage and disposal language for non-refillable sealed containers;
- Revise label so that language contained in brackets [] instead of parentheses () is considered optional or interchangeable.

General Comments:

A stamped copy of the labeling accepted with conditions 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 Velma Noble PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Velma Noble,
Product Manager, Team 31
Regulatory Management Branch
Antimicrobials Division (7510P)

Enclosure

FORMULATION HS-8451P

- DISINFECTANT
- SANITIZER

A concentrated disinfectant for use in hospitals and nursing homes, schools and colleges, medical and dental offices, office buildings, restaurants and bars, federally inspected meat and poultry plants and beverage plants.

Active Ingredient:
 n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)
 dimethyl benzyl ammonium chloride 10.0%
 Other Ingredients: 90.0%
 Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

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

EPA Reg. No. 47371-32
 EPA Est. No. (insert EPA Establishment No. here)
 Net Contents: (insert container size here)

[DOT symbols]
 [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
 EPA Letter Dated:**

JAN 12 2012

~~Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 47371-32~~

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield or safety glasses). Harmful if absorbed through the skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Harmful if swallowed.

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 larger, the following Environmental Hazards statements will be used:

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. 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.



FOR SANITIZING: For use on hard nonporous surfaces such as counter tops, eating utensils and drinking glasses. Remove gross filth and heavy soil deposits by prescrape, prewash, or presoak if necessary. Wash surfaces with detergent or compatible cleaner. Rinse with potable water. Thoroughly wet immobile surfaces with 1 ounce per 4 gallons of water [200 ppm] for a minimum contact time of 1 minute. Immerse mobile items in solution of 1 ounce per 4 gallons of water [200 ppm] for a minimum contact time of 1 minute. All surfaces to air dry. Do not rinse with water. Prepare a fresh solution for each use then discard.

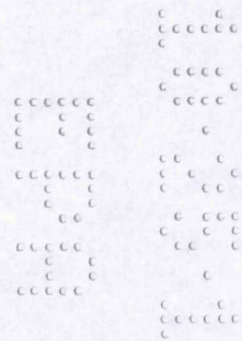
Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

**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 ounce to 4 gallons of water [200 ppm]. 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 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)].

RESTAURANT AND BAR USE: For use as a sanitizer on dishes, glassware, silverware, and cooking utensils. Remove gross filth and heavy soil deposits by prescrape, prewash, or presoak if necessary. Wash surfaces with detergent or compatible cleaner. Rinse with potable water. Thoroughly wet immobile surfaces with 1 ounce per 4 gallons of water [200 ppm] for a minimum contact time of 1 minute. Immerse mobile items in solution of 1 ounce per 4 gallons of water [200 ppm] for a minimum contact time of 1 minute. All surfaces to air dry. Do not rinse with water. Prepare a fresh solution for each use then discard



A.O.A.C. Use-dilution Test

Kills Salmonella enterica, Staphylococcus aureus, Pseudomonas aeruginosa.

An effective sanitizer for use on food contact surfaces; it also fulfills the criteria of *Appendix F of the Grade "A" Pasteurized Milk Ordinance 1999* recommendation of the U.S. Public Health Service in hard waters up to 500 ppm hardness [calculated as CaCO₃].

Use on floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, athletic equipment, garbage cans, lavatory fixtures and other hard nonporous surfaces.

DISINFECTANT: 1:128 1 oz. per gallon of water

SANITIZER: 1:512 1 oz. per 4 gallons of water

DIRECTIONS FOR USE

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

DISINFECTION: Remove gross filth and heavy soil deposits. Pre-clean all surfaces prior to disinfection. Thoroughly wet surfaces with a 1 oz. per gallon of water use solution for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge or cloth as well as with a coarse sprayer or by soaking. 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 is not necessary unless floors are to be waxed or polished.

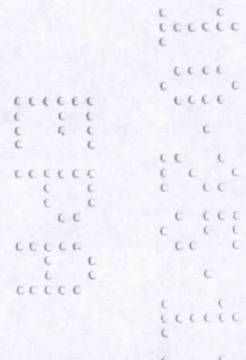
Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

{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.



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 oz. per 4 gallons of water [200 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 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.

SANITARY FILLING: For use in sanitizing bottles or cans in the final rinse application. This formulation is to be proportioned into the final rinse water line of the container washer or rinser in concentration of 200 ppm. A sanitizing solution of 200 ppm active quat should be used in an external spraying application for the filler and closing machine.

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use solution of 1 oz to 4 gallons of water [200 ppm] for final washer and rinser applications. Allow surfaces to remain wet for at least one minute. Drain thoroughly. Do not rinse.

STORAGE TANK SANITIZING: For sanitizing beer fermentation and holding tanks. A solution of 200 ppm should be applied by spraying or used in combination with automated cleaning systems. Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use solution of 1 oz to 4 gallons of water [200 ppm] for final washer and rinser applications. Allow surfaces to remain wet for at least one minute. 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.

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{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.

{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.

{Note to reviewer: Several packaging options are designed for use dilution systems with sealed containers or bottles to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:}

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. Wrap empty container and discard in trash [or offer for recycling].

