

47371-77

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 10 2009

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

SUBJECT: Formulation HTA-64
EPA Registration No.: 47371-77
Amendment Date: June 11, 2009
EPA Receipt Date: June 15, 2009

Dear Ms. Holcombe,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

Proposed Amendment

- Update Storage and Disposal per PRN 2007-4
- Update Company Address and add optional statements

Conditions

Revise the label as follows:

- 1) The Environmental Hazards must be revised to be in agreement with the ADBAC RED by adding the statement, "*This pesticide is toxic to fish and aquatic invertebrates.*"
- 2) The nomenclature for Influenza A/73 (Victoria) and Vaccinia on page 2 is incomplete. You need to indicate that the microorganisms are viruses by stating "for Influenza A/73 *Virus* and Vaccinia *Virus*."
- 3) The first statement under "Sanitary Filling" and "Storage Tank Sanitizing" on page 3 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, recommended. Also, revise the rate to read "175 ppm active quat (2 oz per 3 gallons of water)" and add the statement, "*Allow surfaces to remain wet for at least 1 minute.*"

CONCURRENCES

CONCURRENCES							
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4) Step 6 under "Sanitizing Eating/Drinking Utensils in Eating Establishments" on page 4 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "must."

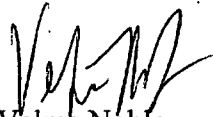
4) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Delete the "Storage and Disposal" Instructions for containers one gallon or less with uses other than household or residential.

General Comments

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

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



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

Enclosure: Stamped Label

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE: Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, safety glasses or face shield), protective clothing and gloves (rubber or chemical resistant) when handling. 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.

(For 5 gallon & larger only)

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 HTA-64

DISINFECTS - DEODORIZERS - SANITIZES

BACTERICIDAL *VIRUCIDAL FUNGICIDAL

Active Ingredients:

n-Alkyl (C₁₄ 60%, C₁₆ 30%, C₁₈ 5%, C₁₂ 5%)
dimethyl benzyl ammonium chloride 1.69%
n-Alkyl (C₁₂ 68%, C₁₄ 32%)
dimethyl ethylbenzyl ammonium chloride 1.69%
Other Ingredients:..... 96.62%
Total: 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-77
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

RECEIVED
SEP 10 2009

47371-77

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An effective, multi-purpose disinfectant cleaner, Staphylocidal, Pseudomonacidal, Bactericidal, Fungicidal, and *Virucidal against Herpes virus Type 1, Adenovirus Type 3, Influenza A/73 (Victoria) and Vaccinia on precleaned, hard, nonporous, environmental surfaces.

Bactericidal against:

Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella enterica

Aeromonas salmonicida
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Listeria monocytogenes
Shigella sonnei
Shigella flexneri
Proteus mirabilis
Pseudomonas putida
Staphylococcus aureus phage 80 & 81
Staphylococcus epidermidis
Streptococcus pyogenes
Vibrio anguillarum

Alternaria tenuis
Fusarium oxysporum
Geotrichum candidum
Penicillium digitatum
Phytophthora infestans
Rhizopus nigricans
Trichoderma harzianum

Mold & Mildewcidal against:

Trichophyton mentagrophytes

For use in hospitals, nursing homes, schools, colleges, office buildings, restaurants, bars, commercial and industrial institutions, veterinary clinics, hotels and motels, animal life science laboratories, medical and dental offices.

Use on previously cleaned, hard, nonporous surfaces such as floors, walls, metal surfaces, glazed porcelain and plastic surfaces, (such as polypropylene, polystyrene).

DISINFECTANT: 1:64 2 oz. per gallon of water
(528 ppm Quat)

SANITIZER: 1:192 2 oz. per 3 gallons of water
(175 ppm Quat)

DIRECTIONS FOR USE

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

FOR DISINFECTING: Remove gross filth and heavy soil deposits, then thoroughly wet surfaces with a solution of 2 oz. per gallon of water. Let solution remain on surface for a minimum contact time of 10 minutes. Can be applied with a mop, sponge, cloth, or coarse spray or by soaking. The 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 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.

TO CONTROL MOLD AND MILDEW: To control mold and mildew on hard, non-porous surfaces, wash visible soil from the surface. Then, apply 1/2 ounce per gallon solution with mop, sponge, cloth or coarse mechanical sprayer so as to wet all surfaces thoroughly for a minimum contact time of 10 minutes. Let air dry. Repeat application every 7 days or more often if growth recurs.

FISHERIES, MILK, CITRUS, ICE CREAM AND POTATO PROCESSING PLANTS: 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 bacteria associated with condensation on equipment and pipes. Follow disinfecting directions.

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 sanitizing directions. When treating conveyors, do not let sanitizer contact food or apply to conveyor when food products or packaging are not present.

FOR SANITIZING: For use on hard, nonporous surfaces, such as counter tops, eating utensils and drinking glasses. 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. Then, use 2 ounces per 3 gallons of water, for a minimum contact time of 1 minute, in a single application. Can be applied with a mop, sponge, cloth, or coarse 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 use solution is prepared fresh for each use, then discarded. Drain thoroughly. Allow to air dry. 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 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. Immerse in solution of 2 oz. per 3 gallons of water for at least 1 minute. Drain thoroughly. Allow to air dry. Do not rinse.

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment. Wash surfaces with compatible detergent and rinse with potable water prior to sanitizing. Fill equipment with solution of 2 ounces per 3 gallons of water (175 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 is to be drained from the system. Allow to air dry. Do not rinse

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 and air dry before using. Do not rinse.

SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. Wash surfaces with compatible detergent and rinse with potable water prior to sanitizing. The product is to be proportioned into the final rinse water line of the container washer or rinser in a concentration of 175 ppm. A sanitizing solution of 175 ppm active quat is to be used in an external application for the filler and closing machine. Follow sanitizing directions.

STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. Wash surfaces with compatible detergent and rinse with potable water prior to sanitizing. A solution of 175 ppm quat is to be applied manually 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.

For Wisconsin Use 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. (A commercial cleaner or detergent can be recommended.)
3. Rinse with potable water.
4. Sanitize in a solution of 2 fluid ounces per 3 gallons of water (175 ppm quat). 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 drain-board to air dry.
6. Fresh sanitizing solution should be prepared at least daily or more often if 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 40 CFR 180.940(a)).

DEODORIZER: Thoroughly wet surfaces using a solution of 2 ounces per gallon of water. Apply with a mop, sponge, cloth, coarse spray, or by soaking. Allow to air dry.

(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household or Residential)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate.

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon)

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 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.

(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. 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.