

47371-8

11-19-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460



Office of Pesticide Programs

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

NOV 19 2009

Attention Mrs. Joanna Holcombe.

Subject: H&S Chemicals Division c/o Lonza Inc.
Registration No.: 47371-8
Amendment Dated: August 18, 2009
Submission #: 857032

Dear Ms. Holcombe,

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

Proposed Amendment

- Add optional barcode, "country of origin" statement and "manufactured in" statement;
- Update the company address;
- Revise Salmonella choleraesuis to its new name Salmonella enterica;
- Revise "Wisconsin State Board of health Directions for Eating Establishment" section;
- Update the Storage and Disposal language per PR Notice 2007-4

Conditions

Revise the label as follows:

- 1) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern.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 w/ uses other than household/residential. Also revise the second "Note to reviewer" to read "*Containers institutional/industrial/ commercial uses.*"
- 2) The Container Rule established rinsate instructions for commercial, institutional, and industrial containers sold in containers five gallons or less and containers greater than five gallons. Therefore, revise the "Container Disposal" statements as follows:
 - a) Your proposed "Container Disposal" statements are acceptable for containers five gallons or less. You need to add the following descriptor above the statement, "*(Containers 5 gallons or less).*"

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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b) If you sell your product in containers greater than 5 gallons, you must add the following statements:

(Container greater than 5 gallons)

Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

- Page 2)**
- Remove the first aid statement from page two and place it on page one.
 - Under the "Environmental Hazard" section please include the statement, "This product is toxic to fish and other aquatic organisms".

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: Stamped Label

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FORMULATION HS-256Q

DISINFECTS DEODORIZES SANITIZES

BACTERICIDAL *VIRUCIDAL FUNGICIDAL

Active Ingredients:

n-Alkyl (C ₁₄ , 60%; C ₁₆ , 30%; C ₁₈ , 5%; C ₁₂ , 5%)	
dimethyl benzyl ammonium chloride	6.75%
n-Alkyl (C ₁₂ , 68%; C ₁₄ , 32%)	
dimethyl ethylbenzyl ammonium chloride.....	6.75%
Other Ingredients:	86.50%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

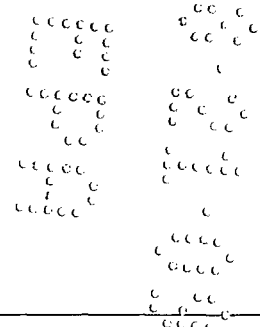
See (side) (back) (right) (left) panel for Precautionary Statements and First Aid.

EPA Reg. No. 47371-8
 EPA Est. No. *(insert EPA Est. No. here)*
 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:

NOV 19 2009
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. *47371-008*



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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER CORROSIVE: Causes irreversible eye damage and skin burns. Harmful if absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, safety glasses or face shield) protective 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.

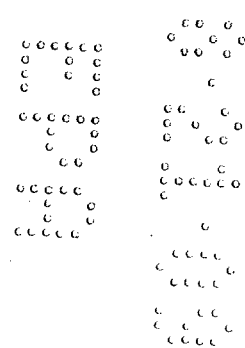
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

(for 5 gallons and larger only)

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.



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 pre-cleaned, hard, nonporous, environmental surfaces.

Bactericidal against:

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

Mold & Mildewcidal against:

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

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

DISINFECTANT: 1:256 1/2 oz. per gallon of water
(527 ppm Quat)

SANITIZER: 1:768 1/2 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 1/2 ounce per gallon of water. Apply with a mop, sponge, cloth, coarse spray or by soaking. Let solution remain on surface for a minimum contact time of 10 minutes. The use solution is prepared fresh for each use, then discarded. Wipe dry with a clean cloth or sponge or allow to air dry. Rinsing 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.

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.

TO CONTROL MOLD AND MILDEW

To control mold and mildew on hard, nonporous surfaces, wash visible soil from the surface. Then apply 1/2 ounce per gallon solution with mop, sponge, cloth or coarse sprayer so as to wet all surfaces thoroughly. Let air dry. Repeat application every 7 days or more often if growth recurs.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1/2 oz. of **FORMULATION HS-256Q** per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. 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. Thoroughly scrub all surfaces that come in contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

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 disinfection directions.

For use as a sanitizer on conveyors and equipment to reduce or eliminate odors in the processing area. Follow directions for sanitizing food contact surfaces. Food products and packaging materials must be removed from the room or carefully protected.

TO SANITIZE FOOD CONTACT SURFACES:

or

TO SANITIZE FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS:

Use **Formulation HS-256Q** to sanitize hard nonporous surfaces of food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage areas and display equipment and other hard surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, pre-scrape or, when necessary, pre-soak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

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.

Apply a use-solution of 1/2 oz. of **Formulation HS-256Q** per 3 gallons of water (or equivalent dilution) to precleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least (60 seconds) (one minute) followed by adequate draining and air drying. Do not rinse.

Prepare a fresh solution for each use. For mechanical application, use-solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard nonporous surfaces by cloth, sponge or brush or coarse spray.

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion.

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 1/2 ounce 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 drain the sanitizing solution from the system.

To insure the removal of flavors during changeover between products, clean with a good detergent or compatible cleaner (A commercial cleaner or detergent may be recommended). Rinse with potable water and flush the system with the sanitizing solution for at least 1 minute. Allow to drain completely before using.

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 1/2 ounce per 3 gallons of water (175 ppm quat). Use a sanitizing solution of 1/2 ounce per 3 gallons of water (175 ppm quat) in an external application for the filler and closing machine.

STORAGE TANK SANITIZING

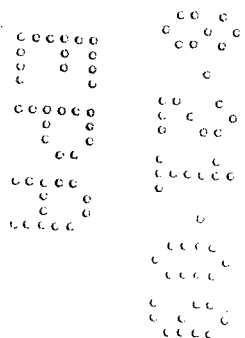
Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of 1/2 oz. of **Formulation HS-256Q** per 3 gallons of water (or equivalent dilution) for mechanical or automated systems. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse. Do not rinse.

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 may be recommended.)
- 3) Rinse with potable water.
- 4) Sanitize in a solution of 1/2 ounce 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 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 HSS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 40 CFR 180.940 (a)).



(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.

