

47371-161

10/7/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/11

Joanna Holcombe
Sr. Regulatory Services Associate
H & S Chemicals Division
c/o Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

OCT 7 2010

SUBJECT: HS-451 Disinfectant/Sanitizer (50%)
EPA Registration No.: 47371-161
Notification Date: September 7, 2010
EPA Receipt Date: September 9, 2010

Dear Ms. Holcombe:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3(c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

- Correct pagination and dating discrepancy in May 18, 2010 label

Based on a review of the submitted information, this notification is acceptable. This notification will be made part of the record for this file.

General Comments

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Tracy Lantz


for

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

7510P:T.Lantz:10/7/2010:47371-161 acceptable notification

CONCURRENCES

SYMBOL	SURNAME	DATE					

 <p style="text-align: center;">United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 47371-161	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HS-451 Disinfectant/Sanitizer (50%)	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) H&S Chemicals Division c/o Lonza Inc. 90 Boroline Road Allendale, NJ 07401 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	

Section - II

- | | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Not Subject to PRIA

Label Notification to correct a pagination and dating discrepancy in the May 18, 2010 stamped label.

This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Joanna Holcombe Date: 9-7-10

Section - III

1. Material This Product Will Be Packaged In:					2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container			4. Size(s) Retail Container 1 oz. to bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled						

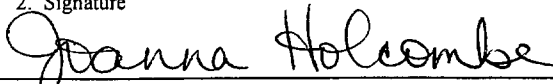
Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name Joanna Holcombe	Title Sr. Commercial Regulatory Services Associate	Telephone No. (include Area Code) 201-316-9297
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Sr. Commercial Regulatory Services Associate	6. Date Application Received (Stamped)
4. Typed Name Joanna Holcombe	5. Date September 7, 2010	

Via FedEx

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2227 S. Crystal Drive
Arlington, VA 22202

Lonza Inc
Allendale
90 Boroline Road
Allendale, NJ 07401, USA

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

Tel 201-316-9297
Fax 201-696-3470
joanna.holcombe@lonza.com

September 7, 2010

**SUBJECT: H&S Chemicals Division c/o Lonza, Inc.
HS-451 Disinfectant/Sanitizer (50%), EPA Reg. No. 47371-161
Application for Label Notification**

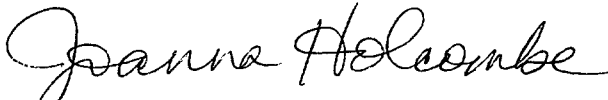
Dear Ms. Noble:

I am submitting an application for a notification to correct a pagination and dating discrepancy in the May 18, 2010 stamped label. Please find the enclosed documents in support of this notification:

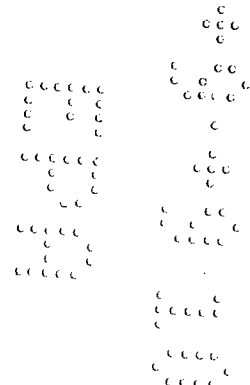
- Application for Notification;
- One copy of the May 18, 2010 stamped label;
- One copy of the proposed label with changes highlighted; and
- Two copies of the proposed label

If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely,



Joanna Holcombe
Sr. Commercial Regulatory Services Associate
Lonza Inc.



HS-451 DISINFECTANT/SANITIZER (50%)

Active Ingredients:

n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)

dimethyl benzyl ammonium chloride..... 50.0%

Other Ingredients: 50.0%

Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

EPA Reg. No. 47371-161

EPA Est. No. (*insert EPA Establishment No. here*)

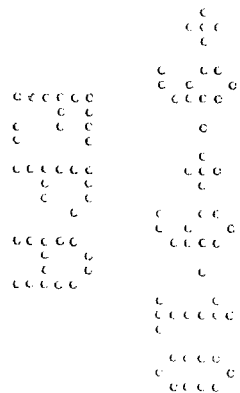
Net Contents (*insert container size here*)

H&S CHEMICALS DIVISION

c/o Lonza Inc.

90 Boroline Road

Allendale, NJ 07401



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND ANIMALS**

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled, swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Do not breathe vapor. Wear protective eyewear (goggles, safety glasses or face shield) 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 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, preferable by mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.

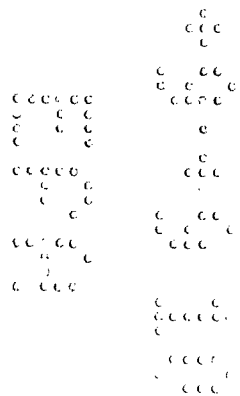
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

(For 5 gallon & larger)

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.



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

For disinfecting/sanitizing precleaned hard, nonporous surfaces in nursing homes, schools, office buildings, farms, restaurants, bars, beverage plants, and federally inspected meat and poultry establishments.

Effective against the representative gram-positive pathogen *Staphylococcus aureus*, the representative gram-negative pathogen *Salmonella choleraesuis*, and the representative hospital pathogen *Pseudomonas aeruginosa*.

USES: Floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, athletic equipment, garbage cans, lavatory fixtures and other hard inanimate nonporous surfaces.

For the preservation of wet-packed (cellulose) sponges.

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DIRECTIONS FOR USE

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

DISINFECTANT 1 oz. per 5 gallons
..... (781 ppm quat)
SANITIZER ¼ oz. per 5 gallons
..... (200 ppm quat)

DILUTION INSTRUCTIONS

For use as a disinfectant at 781 ppm, add 1 ounce (2 tablespoonfuls) in 5 gallons of water.

For sanitizing at 200 ppm, add and stir ¼ ounce (½ tablespoonful) in 5 gallons of water.

FOR DISINFECTING

Pre-clean all surfaces prior to disinfection. Then thoroughly wet surfaces with the required dilution. The solution can be applied with a cloth, mop, sponge, or coarse trigger sprayer, or by soaking. 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 of 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry.

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.

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

Rinsing of floors is not necessary unless the floors are to be waxed or polished.

FOR POULTRY / SWINE HOUSE DISINFECTING:

1. Remove all poultry / swine 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 / swine.
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 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 all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent and rinse with potable water before reuse.
8. All treated equipment that will be in contact with feed or drinking water must be rinsed with potable water before using.

FOR SANITIZING FOOD CONTACT SURFACES

For use on hard nonporous surfaces such as counter tops, eating utensils, and drinking glasses.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, 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.

Thoroughly wet surfaces with a solution of ¼ ounce product per 5 gallons of water. Let the solution remain on surface for a minimum of 1 minute. The solution can be applied with a mop, sponge or cloth as well as by soaking. Apply by soaking to dishes, glasses and eating utensils. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Allow to air dry. Do not rinse.

RESTAURANT AND BAR USE

For use as a sanitizer on dishes, glassware, silverware and 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. Then immerse in a solution of ¼ ounce product per 5 gallons of water for at least 1 minute. Drain thoroughly. Allow to air dry. Do not rinse.

STORAGE TANK SANITIZING

Recommended for sanitizing beer fermentation and holding tanks. Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Use a solution of ¼ ounce product per 5 gallons of water with automated cleaning systems for at least 1 minute. 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. Allow to air dry. 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.

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment. Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Fill equipment with solution of ¼ ounce product per 5 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 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 is to be cleaned, rinsed, and flushed with the sanitizing solution for at least 1 minute. Allow to drain completely before using. Allow to air dry. Do not rinse.

SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. 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 is to be used in an external application for the filler and closing machine. Allow to drain and air dry. Do not rinse.

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FOR USE IN FEDERALLY INSPECTED MEAT AND POULTRY ESTABLISHMENTS as a sanitizer not requiring a rinse.

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

Apply ¼ ounce product (200 ppm active quat) per 5 gallons of water for a 1 minute contact time. Allow to drain and air dry. Do not rinse.

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

TO SANITIZE PREVIOUSLY CLEANED FOOD GRADE EGGS IN SHELL EGG AND EGG PRODUCT PROCESSING PLANTS: Spray with ¼ ounce product per 5 gallons of water (200 ppm active quat) for 1 minute. The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be immediately broken for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be used for sanitizing. Dirty, cracked or punctured eggs cannot be sanitized.

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(Note to Reviewer: The preservation of wet-packaged sponges use will only be used by itself on a commercial label. None of the other uses that are on the HS-451 Disinfectant/Sanitizer (50%) Master Label will be included).

TO PRESERVE WET-PACKED SPONGES (Industrial Use Only)

HS-451 Disinfectant/Sanitizer (50%) can be used to preserve wet-packed sponges only at the point of manufacture of the sponge.

Sponges must be treated with HS-451 Disinfectant/Sanitizer (50%) in an automated system that is designed to prevent dermal and inhalation exposure to workers. Thoroughly wet uncut sponge material with a use-solution of HS-451 Disinfectant/Sanitizer (50%) at a dosing rate of 0.38 – 1.15 ounces of HS-451 Disinfectant/Sanitizer (50%) per gallon of water. The use-solution can be applied by mechanically pouring, drizzling, immersion or by use of a low volume very coarse spray. Mechanically squeeze excess solution from the sponge, leaving the sponge material damp but not dripping. The target incorporation rate for the active ingredient (alkyl dimethyl benzyl ammonium chloride or ADBAC) in the finished sponge is 900-1500 ppm. Mechanically cut sponges to the desired size and seal into polyethylene bags. Do not contact the wet or damp sponges.

Recycle the solution squeezed from the wet sponges into the preservation solution. Prepare a fresh preservation solution as needed.

Wet packed sponge packaging must state "Rinse thoroughly before use (using)".

Sponges may be used on food contact surfaces.

(Note to reviewer: For non-refillable Containers for commercial, industrial and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.)

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. 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.

(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.