

47371-77

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/8

12/30/2009



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 30 2009

Joanna Holcombe  
Sr. Commercial Regulatory Services Associate  
Lonza Inc.  
90 Boroline Road  
Allendale, NJ 07401

Subject: Formulation HTA-64  
EPA Reg. No. 47371-77  
Application Dated: Dec 01, 2009  
Receipt Date: Dec 03, 2009

Dear Joanna Holcombe

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9. is acceptable.

**Proposed Amendment**

Adding marketing language for the Pandemic H1N1

**Comments**

Based on a review of the material submitted, the following comments apply:  
This application for notification to add marketing language for the Pandemic H1N1 is acceptable. A copy has been placed in our records for future reference.

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 Branch1  
Antimicrobial Division (7510P)

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							

<b>EPA</b>	United States	<input type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	

Application for Pesticide - Section 1

1. Company/Product Number <b>47371-077</b>	2. EPA Product Manager <b>Velma Noble</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Formulation HTA-64</b>	PM# <b>31</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Lonza Inc. 90 Boroline Road Allendale, NJ 07401</b>	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	
<input type="checkbox"/> Check if this is a new address		

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.)  
**Notification of label change to add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1**  
**\*Not Subject to PRIA\***  
*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 may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.*

Signature: Joanna Holcombe Date: 12/1/09

Section - III

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

Section - IV

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

Name <b>Joanna Holcombe</b>	Title <b>Sr. Commercial Regulatory Services Associate</b>	Telephone No. (Include Area Code) <b>201-316-9297</b>
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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 <u>Joanna Holcombe</u>	3. Title <b>Sr. Commercial Regulatory Services Associate</b>	6. Date Application Received  (Stamped)
4. Typed Name <b>Joanna Holcombe</b>	5. Date <b>December 1, 2009</b>	



Via FedEx

Ms. Velma Noble, PM-31  
Document Processing Desk (NOTIFY)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 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

December 1, 2009

**SUBJECT: Formulation HTA-64, EPA Registration No. 47371-077  
Application for Label Notification**

Dear Ms. Noble:

The purpose of this notification is to add the following:

**Add optional marketing language per EPA Guidance for Testing and Labeling Claims  
against Pandemic 2009 H1N1.**

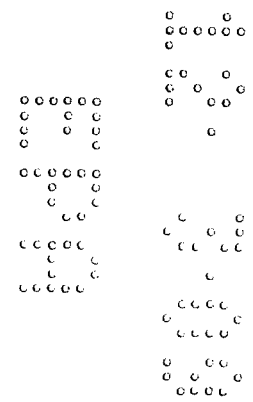
Please find enclosed the following documents in support of this label notification.

- Application for Pesticide Notification
- One copy of the label with changes highlighted

Please provide your decision electronically to me at [joanna.holcombe@lonza.com](mailto:joanna.holcombe@lonza.com) and subsequently send me a letter confirming the Agency's decision. If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely,  
Lonza Inc.

Joanna Holcombe  
Sr. Commercial Regulatory Services Associate



**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**

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.

**FORMULATION HTA-64**

**DISINFECTS - DEODORIZERS - SANITIZES**

**BACTERICIDAL \*VIRUCIDAL FUNGICIDAL**

**Active Ingredients:**

n-Alkyl (C <sub>14</sub> 60%, C <sub>16</sub> 30%, C <sub>18</sub> 5%, C <sub>12</sub> 5%)	
dimethyl benzyl ammonium chloride.....	1.69%
n-Alkyl (C <sub>12</sub> 68%, C <sub>14</sub> 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)*

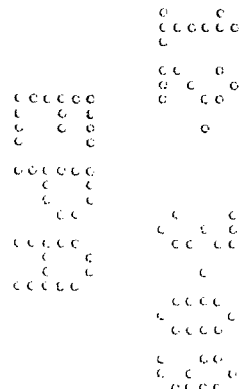
Net Contents *(insert container size here)*

[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



An effective, multi-purpose disinfectant cleaner, Staphylocidal, Pseudomonacidal, Bactericidal, Fungicidal, and \*Virucidal against Herpes virus Type I, Adenovirus Type 3, Influenza A/73 Virus (Victoria) and Vaccinia Virus 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:**

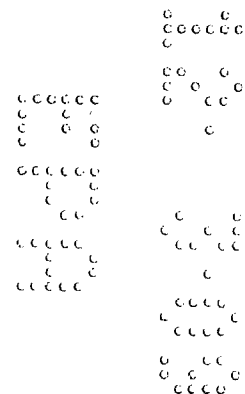
Trichophyton mentagrophytes

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).

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

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.



**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 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.

**TO CONTROL MOLD AND MILDEW:** To control mold and mildew on hard, non-porous surfaces, wash visible soil from the surface. Then, apply ½ 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:** 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 (2 oz per 3 gallons of water) is to be used in an external application for the filler and closing machine. Allow surfaces to remain wet for at least 1 minute. Follow sanitizing directions.

**STORAGE TANK SANITIZING:** 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 (2 oz per 3 gallons of water) 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. Allow surfaces to remain wet for at least 1 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.

*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 must 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 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 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.