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



# United States Environmental Protection Office of Pesticide Programs Agency

APR 8 2010

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

Subject:

Formulation HS-256Q

Registration No.:

47371-008

**Notification Date:** 

March 10, 2010

**EPA Receipt Date:** 

March 11, 2010

Submission #:

429982

Dear Ms. Holcombe,

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

### **Proposed Notification**

• Update H1N1 Labeling Claim

### **General Comments:**

Based on a review of the submitted materials, your notification for "Formulation HS-256Q", EPA Reg. 47371-008, as listed, 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 PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Ousella Copeland

Velma Noble,

Product Manager, Team 31

Regulatory Management Branch

Antimicrobials Division (7510P)

CONCURRENCES										
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EDA	United States	☐ Re	gistration	OPP Identifier Number		
<b>EPA</b> Environ	mental Protection Agen	cy 🗌 An	nendment			
	Washington, DC 20460	⊠ Oti	her			
	Application	on for Pesticide - Sect				
Company/Product Number		2. EPA Product Manager		3. Proposed Classification		
47371-008		Velma Noble	•			
4. Company/Product (Name)		PM#	None Restricted			
Formulation HS-256Q	7ID (C. 1-)	( Fundited Pariser, Inc.	2/2)/h)/f)			
<ol> <li>Name and Address of Applicant (Include H&amp;S Chemicals Division</li> </ol>	e ZIP Code)	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:				
c/o Lonza Inc.			<b>-</b>			
90 Boroline Road		EPA Reg. No.				
Allendale, NJ 07401		Product Name				
Check if this is a new address						
		Section – II				
Amendment - Explain below.		Final prin	ted labels in response to Age	ncy letter dated		
Resubmission in response to Agend	cy letter dated	"Me Too" Application				
Notification - Explain below.		Other - E	xplain below			
Explanation: Use additional pa						
Notification of label char	_			r Testing and Labeling		
	Claims aga	inst Pandemic 2009	H1N1			
		t Subject to PRIA*				
This notification is consistent with t						
to the labeling or the confidential st false statement to EPA. I further un						
product may be in violation of FIFF						
produce may be in violation of 111	at and may be subject to enje					
Signature:	nna Hollon	be	Date: 3-10-	70		
<i>U</i>						
		Section – III				
Material This Product Will Be Packa						
Child-Resistant Packaging	Unit Packaging	Water Soluble	e Packaging	2. Type of Container		
Yes*	∐ Yes	Yes		Metal		
∐No	No No	No Le "Vee"	NT	Plastic		
*Certification must be		lo. per If "Yes" ontainer Package wgt.	No. per container	Glass		
submitted	· · · · · · · · · · · · · · · · · · ·			Paper		
				Other (Specify)		
3. Location of Net Contents Information		Container	5. Location of L	abel Directions		
Label Contain	er		On Label			
6. Manner in Which Label is Affixed to	Product Lithogr	aph Ot		g accompanying product		
o. Maine in which Laber is Affixed to	Paper g	•	<u> </u>			
	Stencile			_		
		Section – IV				
1. Contact Point (Complete items direction)	ly below for identification of ind	ividual to be contacted, if nec	essary, to process this appli	cation)		
Name	Title			Telephone No. (Include Area Code)		
Joanna Holcombe	Sr	. Commercial Regulatory	Services Associate	201-316-9297		
	O- 1:6 1:			6. Date Application Received		
I certify that the statements I have made	Certification	thereto are true, accurate and	complete Lacknowledde C	6. Date Application Received		
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge (						
2 Signature	/ 3. Ti	<del></del>				
Janua Halas						
4. Pyped Name	mbe Sr. 5. Da	<b>Commercial Regulatory</b>	Services Associate			

Lonza

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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

March 10, 2010

SUBJECT: Formulation HS-256Q, EPA Registration No. 47371-008
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 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

banna Holsombe

### **FORMULATION HS-256Q**

### **DISINFECTS DEODORIZES 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	6.75%
n-Alkyl (C <sub>12</sub> , 68%; C <sub>14</sub> , 32%)	
dimethyl ethylbenzyl ammonium chloride	6.75%
Other Ingredients:	<u>86.50%</u>
Total:	

### 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. (<u>insert EPA Est. No. here</u>)
Net Contents (<u>insert container size here</u>)
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

H&S CHEMICALS DIVISION c/o LONZA INC. 90 Boroline Road Allendale, NJ 07401



## 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)

This product is toxic to fish and other aquatic organisms. 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 precleaned, hard, nonporous, environmental surfaces.

### **Bactericidal against:**

Streptococcus pyogenes Vibrio anguillarum

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

### Mold & Mildewcidal against:

Alternaria tenius
Fusarium oxysporum
Geotrichum candidum
Penicillium digitatum
Phytophthora infestans
Rhizopus nigricans
Trichoderma harzianum
Trichophyton mentagrophytes

Respiratory illnesses attributable to Pandemic 2009 H1N1are 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.

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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.

FORMULATION HS-256Q EPA REG. NO. 47371-8 EPA STAMPED LABEL 11-19-09, DRAFT 3-10-10

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### 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.

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# 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 <u>not permitted</u> 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, institutional/industrial/commercial uses)

### 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 is five gallons or less)

### 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.

### (Container is over five gallons)

### **Container Disposal:**

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. 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. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning available, puncture and dispose in sanitary landfill. 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.

FORMULATION HS-256Q EPA REG. NO. 47371-8 EPA STAMPED LABEL 11-19-09, DRAFT 3-10-10

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