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



United States Environmental Protection Office of Pesticide Programs Agency

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

Subject:

Formulation HS-652O

Registration No.:

47371-006

Notification Date:

March 10, 2010 March 11, 2010

EPA Receipt Date: Submission #:

429981

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-652Q", EPA Reg. 47371-006, 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.

Dusilla Copeland

Velma Noble,

Product Manager, Team 31 Regulatory Management Branch

Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL					***********		
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47371-006			Velma Noble					
4. Company/Product (Name) Formulation HS-652Q			PM# 31			None None	Restricted	
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	nicals Division		or identical in composition and labeling to:					
c/o Lonza 90 Borolir			EPA Reg. No.					
Allendale,			Product Name					
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Amendment - E	explain below.			Final printed labe	ls in response to Ag	ency letter dated		
	n response to Agency letter of	dated	"Me Too" Application					
Notification - E			Other - Explain below					
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Notification	n of label change to	-	_			or Testing and l	Labeling	
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This notification is	consistent with the provi		ot Subject 1 08-10 and EPA		FR 152 46 and i	no other changes ha	we heen made	
to the labeling or t	he confidential statement	t of formula of this p	roduct. I unde	erstand that it is a vie	olation of 18 U.S.	C. Sec. 1001 to will	lfully make any	
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3. Location of Net C Label	Container	4. Size(s) Retail	Container		On Label	Label Directions		
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6. Manner in Which	Label is Affixed to Product		•	Other				
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1. Contact Point (Con	mplete items directly below	for identification of inc	dividual to be co	entacted, if necessary, i	to process this appl	lication)	-	
Name				15 11 0		Telephone No. (Inc	ude Area Code)	
Joanna Holcomi	be	S	r. Commercia	Regulatory Service	es Associate	[261-316-9297 °		
		Certification	<u> </u>		i, (f	c 6. Date Applie	ation Received	
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4. Typed Name	h.a	1	Date					
Joanna Holcom	UC	IV.	March 10, 2010					

Lonza

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-652Q, EPA Registration No. 47371-006
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

Janna Holcombe

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE: Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber or chemical resistant). Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, chewing gum or using tobacco.

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 gallon & larger)

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 HS-652Q

One-Step Germicidal Cleaner

- DISINFECTANT
- PSEUDOMONACIDAL
- STAPHYLOCIDAL
- SALMONELLACIDAL
- BACTERICIDAL
- FUNGICIDAL
- MILDEWSTATIC
- *VIRUCIDAL

Active Ingredients:	
Didecyl dimethyl ammonium chloride	7.5%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%)	
dimethyl benzyl ammonium chloride	5.0%
Other Ingredients:	<u>87.5%</u>
Total:	

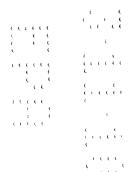
KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No. 47371-6
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



A multi-purpose, germicidal detergent effective in the presence of a moderate amount of organic soil (5% serum). Disinfects, cleans and deodorizes in one labor saving step.

Effective against the following pathogens: (Bacteria:)
Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella enterica

Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Proteus mirabilis
Proteus vulgaris
Serratia marcescens
Shigella flexneri
Shigella sonnei
Staphylococcus aureus phage 80 & 81
Staphylococcus epidermidis
Streptococcus pyogenes

(Viruses:)

*Adenovirus Type 3

*Herpes simplex Virus Type 1

*HIV-1 (AIDS virus)

*Influenza A/Texas Virus

*Rubella Virus (German Measles)

*Vaccinia Virus

(Animal Viruses:)

*Avian influenza Virus

*Bovine rhinotracheitis virus

*Infectious bronchitis Virus (Avian IBV)

*Newcastle disease virus

(Fungi:)

Aspergillus flavus
Aspergillus fumigatus
Aspergillus glaucus var. tonophilus
Candida albicans
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, medical clinics, dental offices, office buildings, hotels, motels, airports, veterinary clinics, farm premises, poultry houses, federally inspected meat and poultry plants and households. Cleans, disinfects and deodorizes floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring, lavatory fixtures, plastic surfaces (such as polypropylene, polystyrene), and other hard, nonporous surfaces.

FORMULATION HS-652Q EPA REG. NO. 47371-006 EPA STAMPED LABEL 9-10-09 WITH 12-30-09 NOTIFICATION, DRAFT 3-10-10 [If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.]

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DILUTION: 1:256

1/2 oz per gallon of water (488 ppm active quat)

DIRECTIONS FOR USE

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

DISINFECTION AND CLEANING: Remove heavy soil deposits from surface, then thoroughly wet surface with a solution of 1/2 ounce of the concentrate per gallon of water. The solution can be applied with a cloth, mop, sponge, or coarse sprayer or by soaking. Let solution remain on surface for a minimum of 10 minutes. Rinse or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

(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 and dishes as a disinfectant.

USDA: Use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas, and / or exterior areas. Follow disinfection directions.

USDA: Use in federally inspected meat and poultry plants as a floor and wall cleaner in all departments. Food products and packaging materials must be removed from the room or carefully protected. Follow disinfection directions.

TOILET BOWLS: To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first remove or expel over the inner trap the residual bowl water. Pour in 3 ounces of the diluted solution. Swab the bowl completely using a scrub brush or mop, making sure to get under the rim. Let stand for 10 minutes or overnight, then flush.

MILDEWSTATIC INSTRUCTIONS: Will effectively control the growth of mold and mildew, plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors and table tops. Apply solution (1/2 ounce per gallon of water) with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

*KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human immunodeficiency virus Type 1 (HIV-1)(associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal Protection: Disposable protective gloves, gowns, face masks and eye coverings as appropriate must be worn during all cleaning of blood / body fluids, and during decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces and objects before application.

Contact Time: Leave surface wet for 5 minutes at 25°C (room temperature). Use a 10-minute contact time for other viruses, fungi and bacteria listed.

Disposal of Infectious Materials: Blood / body fluids must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

FARM PREMISE AND POULTRY HOUSE DISINFECTANT

- 1. Remove all animals and feeds from premises, trucks, coops, crates and enclosures.
- Remove all litter and manure from floors, walls, surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
- 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 all surfaces with the disinfecting solution for a period of 10 minutes.
- 6. 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.
- Ventilate buildings, coops, cars, boats and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
- 8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automated feeders, fountains and waterers with soap and detergent, and rinse with potable water before reuse.

(Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

(Note to reviewer: For Nonrefillable Container for commercial, industrial, and institutional 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 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.

FORMULATION HS-652Q EPA REG. NO. 47371-006 EPA STAMPED LABEL 9-10-09 WITH 12-30-09 NOTIFICATION, DRAFT 3-10-10

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