

6836-169

12/15/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 15 2010

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

SUBJECT: Lonza Formulation P-6
EPA Registration Number: 6836-169
Application Dated: November 29, 2010
Receipt Date: November 30, 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 and 40 CFR 152.46.

- To add "Combustible" to the Physical or Chemical Hazards Section.

Based on a review of the submitted information, this notification is acceptable. A copy has been inserted in your file for future reference.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,

DHE for

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2019

EPA	Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section 1

1. Company/Product Number 6836-169	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulation P-6	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401	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.)

Not Subject to PRIA

Label Notification to add "Combustible" to Physical or Chemical Hazards as requested in the November 10, 2010 EPA formulation approval letter for this product.

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: 11-29-10

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	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input checked="" type="checkbox"/> Plastic	
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		<input type="checkbox"/> Glass	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) <u>bag-in-box</u>	
				<input checked="" type="checkbox"/> On Label	
				<input checked="" type="checkbox"/> On labeling accompanying product	

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
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.		6. Date Application Received (Stamped)
2. Signature <u>Joanna Holcombe</u>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date November 29, 2010	

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Via FedEx

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

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

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

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

November 29, 2010

**SUBJECT: Lonza Formulation P-6, EPA Reg. No. 6836-169
Application for Label Notification**

Dear Ms. Noble:

I am submitting an application to add "**Combustible**" to the Physical or Chemical Hazards section as requested in the November 10, 2010 EPA formulation approval letter for this product. Please find the enclosed documents in support of this notification:

- Application for Notification;
- Copy of the November 10, 2010 EPA formulation approval letter;
- 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,
Lonza Inc.

Joanna Holcombe
Sr. Commercial Regulatory Services Associate

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LONZA FORMULATION P-6

PINE ODOR
DISINFECTANT-CLEANER-DEODORANT

*Kills Pseudomonas, Salmonella and Staphylococcus

**Virucidal

**Kills Influenza and Herpes Viruses

Active Ingredients:

Pine oil	3.95%
Alkyl (C ₁₄ , 58%; C ₁₆ , 28%; C ₁₂ , 14%) dimethyl benzyl ammonium chloride.....	1.97%
Other Ingredients	<u>94.08%</u>
Total:	100.00%

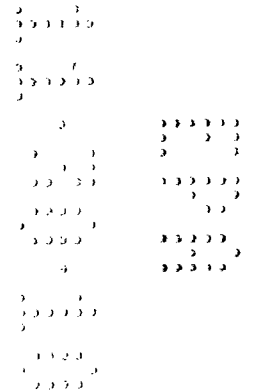
KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 6836-169
 EPA Est. No. (As indicated on container)
 Net Contents: (As indicated on container)
 [Country of origin (insert country)]
 [Manufactured in (insert country)]
 [Barcode]

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. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid contamination of food. Wear protective eyewear (goggles, face shield or safety glasses) protective clothing and rubber gloves. 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.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish and aquatic invertebrates.

(Note to reviewer: If the container size is 5 gallons or greater, the following statements will also be used:)

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.

PHYSICAL OR CHEMICAL HAZARDS:

Combustible. Do not use or store near heat or open flame.

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

- Concentrate (Concentrated)
- Disinfectant (Disinfects)
- Deodorant (Deodorizes)
- Cleaner (Cleans)

Use **LONZA Formulation P-6** in homes, (households), hospitals, medical and dental offices, nursing homes, healthcare facilities, day care centers, nurseries, restaurants, bars, cafeterias, (institutional) kitchens, food processing plants, food storage areas, convenience stores, institutional facilities, public rest rooms, institutions, schools, colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, bathrooms, public facilities, veterinary offices, animal care and animal laboratory facilities, zoos, pet shops, kennels, transportation terminals, hotels and motels, factories, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis and airplanes.

Use **Lonza Formulation P-6** on: washable hard nonporous surfaces: floors, walls, cabinets, counters (countertops), stoves (stovetops), sinks, appliances, microwave ovens (exterior), and refrigerators (exterior), high chairs, tables, picnic tables, outdoor furniture, chairs, desks, telephones, door knobs, garbage cans, bathtubs, shower stalls, shower walls, glass shower doors, tubs and glazed tiles, urinals, toilets, toilet bowls, toilet bowl surfaces, chrome fixtures, other bathroom fixtures, and hard nonporous surfaces made of metal, stainless steel, chrome, glazed porcelain, glazed ceramic, linoleum, sealed stone, fiberglass and plastic (such as polystyrene, polypropylene) enameled surfaces, finished woodwork, vinyl and plastic upholstery,

Lonza Formulation P-6:

- is effective against a wide variety of gram-positive and gram-negative bacteria.
- is an excellent deodorant
- (and) is (especially) effective in controlling odors that are bacterial in origin.
- mixes with water to form clear, stable use solutions.
- has a pleasant pine odor.
- may be used through automatic floor scrubbing equipment.
- Is for use in industrial, commercial and / or medical areas.

Use Lonza formulation P-6 for:

- cleaning and deodorizing.
- one-step cleaning and disinfection.
- disinfection of precleaned, hard nonporous surfaces.

Use solutions are non-corrosive and non-staining to plastic, vinyl, synthetics, enamel & tile and most common metals.

*Effective at 6 oz. per gallon of water against *Pseudomonas aeruginosa* PRD-10, *Salmonella enterica* ATCC 10708, and *Staphylococcus aureus* ATCC 6538 when tested by the A.O.A.C. Use Dilution Test Method for precleaned, hard nonporous surfaces.

**An effective virucide at 6 oz. per gallon of water against Herpes Simplex Virus Type 2 and Influenza Virus Type A/Brazil.

When applied as directed to precleaned hard, nonporous surfaces, Lonza Formulation P-6 also kills the following organisms at 6 ounces per gallon:

- Candida albicans
- Enterobacter aerogenes
- Escherichia coli,
- Shigella sonnei.
- Streptococcus pyogenes

(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.

DIRECTIONS FOR USE

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

APPLICATION INFORMATION

Select the proper use-dilution of Lonza Formulation P-6 from the directions below.

Apply the use-solution with a clean mop, sponge, cloth, squeegee, or mechanical scrubber. For disinfection, thoroughly wet the surfaces to be treated. Surfaces must remain moist for at least 10 minutes to assure proper germicidal action. 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 this product on utensils, glassware or dishes.

Prepare fresh use solutions daily. Do not reuse solutions. Discard solutions when they become visibly soiled.

CLEANING

To Clean and Deodorize or to Preclean Prior to Disinfection. Depending on the soil level of the area to be cleaned, use 3 to 12 oz. of Lonza Formulation P-6 per gallon of water.

DISINFECTING

Hospitals, Healthcare Facilities (Clinics), Nursing Homes: Use 7½ oz. of Lonza Formulation P-6 per gallon of water (1 part to 16 parts water) for one-step cleaning and disinfection of areas with light to medium soil loads. For heavily soiled areas, preclean as described above and then disinfect with 6 oz. of Lonza Formulation P-6 per gallon of water (1 part to 20 parts water).

(Note to reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must 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 to be used on medical device surfaces.

Schools, Industrial areas, Homes, Barber Shops, Restrooms, Restaurants, Food and Meat Processing Plants (non-food, processing areas), Public Rooms, Other Non-Medical use sites: Preclean surfaces. Then, disinfect with a use-solution of 4 oz. of Lonza Formulation P-6 in a gallon of water (1 part to 32 parts water). Alternatively, clean and disinfect in one operation using 7½ oz. of Lonza Formulation P-6 per gallon of water.

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DEODORIZING: garbage cans, garbage trucks, Industrial waste receptacles and garbage handling equipment, it is especially important to preclean for the product to perform properly. Then, apply a wetting concentration of 16 oz. of Lonza Formulation P-6 per gallon of water.

FOR MILDEW CONTROL: Follow directions for hospital disinfection. Repeat treatment every seven days, or more often if new growth appears.

FUNGICIDAL ACTIVITY - At 7 ½ oz. per gallon of water (or equivalent dilution) this [product is effective against *Candida albicans* on hard non-porous surfaces.

TOILET BOWL / URINAL DISINFECTANT AND CLEANER DIRECTIONS:

Empty toilet bowl or urinal and apply a 7 ½ oz per gallon of water use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Brush or swab thoroughly and allow to stand for 10 minutes and flush.

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

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. 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. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with a use-solution of 7 ½ oz. of Lonza FORMULATION P-6 per gallon of water (1 part to 16 parts water) (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

VEHICLES: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and this product. Use 7 ½ ounces of this product per gallon of water to treat vehicles. Leave all surfaces wet for 10 minutes or more.

SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION / VIRUCIDE* / DIRECTIONS:

Mix 7 1/2 oz. of Lonza Formulation P-6 per gallon of water (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

(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 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 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.)

(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.