

6836-97

04-06-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 6 2010

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

Subject: **Benzethonium Chloride USP**  
EPA Registration Number 6836-97  
Notification Dated March 5, 2010  
EPA Received Date March 8, 2010

Dear Ms. Holcombe:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

**Proposed Amendment:**

- Container Disposal Statements. per PR Notice 2007-4

**General Comments:**

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

*Drusilla Copeland*

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

**CONCURRENCES**

SYMBOL								
SURNAME								
DATE								

<b>EPA</b> Environmental Protection Agency Washington, DC 20460	Unit <input type="checkbox"/> ates <input type="checkbox"/> Registratic <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 <b>6836-097</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>Benzethonium Chloride USP</b>	PM# <b>31</b>	
5. Name and Address of Applicant (Include ZIP Code) 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 update Storage and Disposal language per PR Notice 2007-4.

**PLEASE READ COVER LETTER FOR DETAILS.**

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: 3-5-10

**Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No  <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No  If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No  If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <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	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input type="checkbox"/> On Label <input 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 <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.

6. Date Application Received

(Stamped)

2. Signature <u>Joanna Holcombe</u>	3. Title <b>Sr. Commercial Regulatory Services Associate</b>	(Stamp area)
4. Typed Name <b>Joanna Holcombe</b>	5. Date <b>March 5, 2010</b>	

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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  
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

Joanna Holcombe  
March 5, 2010

**SUBJECT: Benzethonium Chloride USP, EPA Reg. No. 6836-097  
Application for Label Notification**

Dear Ms. Noble:

I am submitting an application to update the company address and the Storage and Disposal language per PR Notice 2007-4. This manufacturing use product is shipped in nonrefillable containers greater than 5 gallons, so PR Notice language for commercial/industrial/institutional use containers of that size was used on the label.

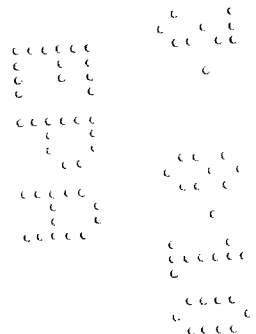
Please find the enclosed documents in support of this notification:

- Application for Notification;
- 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





90 BOROLINE ROAD  
 ALLENDALE, NEW JERSEY 07401 USA  
 EMERGENCY TEL. NO. 309-697-5400

HEALTH	3
FLAMMABILITY	1
REACTIVITY	0
PERSONAL PROTECTION	

# BENZETHONIUM CHLORIDE USP

For Use By Manufacturers Only In Formulating Antimicrobial Products For The Uses Indicated On The Label

Active Ingredient: Diisobutylphenoxyethoxy Ethyl Dimethyl Benzyl Ammonium Chloride Monohydrate.....98.8%  
 Other Ingredients: .....1.2%  
 .....100.0%

CAS. NO. 121-54-0  
 EPA Reg. No. 6836-197  
 EPA EST No. 48210-JP-01

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

**DOT**  
 NOT REGULATED  
 (NON-HAZARDOUS)

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER! 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 a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C. Wear protective eyewear (goggles 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 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. Call a poison control center or doctor for treatment advice.  
**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.  
**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 a 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.

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 convulsion may be needed.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish. 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**

**DO NOT USE OR STORE NEAR HEAT OR FLAME!**

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product is a concentrate for formulating purposes only. This product for formulation into antimicrobial products for use on hard non-porous surfaces in/on Agricultural premises and equipment, Food Handling/storage establishment premises and equipment, Commercial, institutional and industrial premises and equipment, Residential premises and Medical Premises and equipment and for use in/on pressure/thermal and non-pressure Wood treatment, Industrial processes and water systems and Swimming Pools. Formulators using this product are responsible for providing data for the EPA registration of their formulated products. This product may be used to formulate products for specific use(s) not listed on this label if the formulator or primary registrant has complied with U.S. EPA data requirements regarding the support of such use(s).

**NOTE:** This product should not be used or compounded with any reducing or oxidizing agents (such as calcium hypochlorite, solid perchlorate, or nitric acid) since such mixtures may be explosive. Do not use in conjunction with soap or any anionic wetting agent. In preparing packaging mixes containing Benzethonium Chloride USP use normal precautions for handling powdered materials likely to create dust. Use an exhaust fan to keep dust away from operators.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE**

Do not store on side.

**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.

*(Note to reviewer: The product could be in either a liner or a flexible IBC bag, which could then be in either a fiber drum, pail or box.)*

**CONTAINER DISPOSAL**

Nonrefillable container. Do not reuse or refill empty [box.] [drum.] [pail.] or [liner] [flexible IBC bag]. Completely empty [liner] [flexible IBC bag] by shaking and tapping sides and bottom to loosen clinging particles. Then offer for recycling if available or dispose of [box.] [drum.] [pail.] and [liner] [flexible IBC bag] in a sanitary landfill or incinerate if allowed by State and local authorities.

FOR HELP IN A CHEMICAL EMERGENCY CALL CHEMTREC 1-800-424-9300.

BEFORE USING CONSULT MATERIAL SAFETY DATA SHEET.

CODE NO. (P)
LOT NO. (S)
WEIGHT. (Q)
lb. kg.
NUMBER:

CONSHOHOCKEN, PA

ALLENDALE, NJ

MAPLETON, IL

PASADENA, TX

WILLIAMSPORT, PA

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