3/2/2010 UNITED TATES ENVIRONMENTAL PROTECTION GENCY

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

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SUBJECT:

Lonza Mildew Preventative EPA Registration Number: 6836-30 Application Date: December 11, 2009 Receipt Date: December 15, 2009

Dear Ms. Joanna Holcombe:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

1) Revise the Precautionary Statements to be in agreement with the Label Review Manual as follows: "...Wash thoroughly with soap...before eating, drinking, *using tobacco or using the toilet*. Remove contaminated..."

2) Add the following to the Environmental Hazards statements such that this section will reflect the environmental concerns associated with this active ingredient: *"This pesticide is toxic to fish and aquatic invertebrates.* Do not discharge..."

3) As per PR Notice 2000-5, use solution concentrations are not recommended. Use concentrations are directions for the use of the product and as such are stated in mandatory language. Revise the last statement in the second section on page three to read as follows, deleting the word recommended: "For *use* solution concentration, <u>see</u> Use-Directions."

4) Information pertaining to the specific rate at which the product is used are part of the Directions for Use. The fifth section on page three belongs in the Directions for Use section of the label. Place the section beginning: "At 2 ¼ oz. LONZA MILDEW..." and ending: "...and Staphylococcus aureus (ATCC No. 6538)" in the Directions for Use section.

| CONCURRENCES | | | | | | | | |
|-------------------|--|--|--|--|--|-------|--|--|
| SYMBOL 7510P | | | | | | ***** | | |
| SURNAME (1) Land | | | | | | | | |
| DATE 227/2010 | | | | | | | | |

EPA Form 1320-1A (1/90)

OFFICIAL FILE COPY

5) The Precautionary Statements are based on product toxicity and advise the user in the proper handling of this product. Statements in other sections of the label must agree with the Precautionary Statements. Revise the statement immediately preceding the Directions for Use heading by changing "It should be handled with care." to read "It should be handled *according to the Precautionary Statements*."

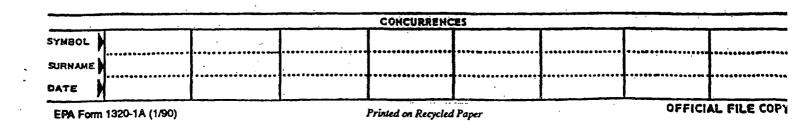
General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

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

7510P:T.Lantz:2/27/10:6836-30



LONZA MILDEW PREVENTATIVE

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Twin-Chain Quaternary Ammonium Compound Concentrate

Mildew Inhibitor for Commercial and Institutional Use With Sanitizing and Residual Bacteriostatic and Self-Sanitizing Activity*

| Active Ingredient: | |
|------------------------------------|--------------|
| Didecyl dimethyl ammonium chloride | . 50% |
| Other Ingredients: | . <u>50%</u> |
| Total: | 100% |

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KEEP OUT OF REACH OF CHILDREN

DANGER

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

*Under humid or wet contamination conditions. See side panel for further comments.

EPA Reg. No. 6836-30 EPA Est. No. (insert EPA Establishment No. here) Net Weight (insert container size here) [Country of origin (insert country)] [Manufactured in (insert country)] [Barcode]

> LONZA INC. 90 Boroline Road Allendale, NJ 07401

ACCEPTED with COMMENTS in EPA Letter Dated:

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-330

LONZA MILDEW PREVENTATIVE EPA REG. NO. 6836-30 EPA STAMPED LABEL 3-1-04, DRAFT 12-11-09

PAGE 1 OF 4

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS ANDDOMESTIC ANIMALS

DANGER! CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, safety glasses or face shield), protective clothing and protective gloves (rubber or chemical resistant). May be fatal if swallowed or inhaled. Do not breathe vapor. Wear a MSHA/NIOSH-approved dust/mist filtering respirator number TC-21C or a NIOSH approved respirator with any N, R, P, or HE filter. Harmful if absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash 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.

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.

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.

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

ENVIRONMENTAL HAZARDS

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.

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ACCEPTED with COMMENTS in EPA Letter Dated: MAR [2 2010]

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No 6836-30

LONZA MILDEW PREVENTATIVE EPA REG. NO. 6836-30 EPA STAMPED LABEL 3-1-04, DRAFT 12-11-09 LONZA MILDEW PREVENTATIVE is based on a highly-active, Twin-Chain, quaternary, ammonium compound. It prevents musty odors and discoloration on all fabrics due to molds, mildew and fungi. At the same time, LONZA MILDEW PREVENTATIVE will sanitize the fabric, and impart a residual self-sanitized and residual bacteriostatic finish to the laundered article.

The mildew inhibition of LONZA MILDEW PREVENTATIVE lasts at least four weeks when used as directed. It is designed for commercial and institutional laundry use by addition to the final rinse or sour step. Fabric may also be preserved against mildew by soaking in a solution of LONZA MILDEW PREVENTATIVE. For recommended solution concentration, see Use-Directions.

The laundering of fabric may not eliminate the odor causing bacteria commonly found in soiled fabrics, such as diapers, hospital and institutional linen and athletic apparel. These bacteria can survive commonly used laundering procedures and remain in finished, "clean" fabrics. LONZA MILDEW PREVENTATIVE, when used at recommended levels, will sanitize such fabrics. Sanitizing is defined as a greater than 99.9% reduction in bacteria count on contaminated fabric.

At the same time LONZA MILDEW PREVENTATIVE imparts to the laundered, sanitized fabric, a residual selfsanitizing and residual bacteriostatic finish. This finish will effectively protect the fabric against rapid bacterial growth caused by moisture and wet contamination. The residual bacteriostatic action of LONZA MILDEW PREVENTATIVE inhibits the growth of bacteria. Its residual self-sanitizing activity reduces the number of bacteria from wet contamination.

At 2¼ oz. LONZA MILDEW PREVENTATIVE per a maximum total of 60 gallons (500 lbs.) of water and a maximum of 100 pounds of fabric (dry weight)., LONZA MILDEW PREVENTATIVE will sanitize and impart to the fabric a residual self-sanitizing and residual bacteriostatic finish. These activities have been confirmed against Klebsiella pneumoniae (ATCC No. 4352) and Staphylococcus aureus (ATCC No. 6538).

All of the above beneficial activity - mildew protection, sanitizing, residual self-sanitizing, residual bacteriostatic - occur when the fabric is treated as directed.

LONZA MILDEW PREVENTATIVE is economical to use because it is concentrated. It should be handled with

DIRECTIONS FOR USE

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

For 4-week protection mildew prevention, to sanitize and to impart to the fabric a residual self-sanitizing and residual bacteriostatic finish use LONZA MILDEW PREVENTATIVE as directed.

COMMERCIAL AND INSTITUTIONAL LAUNDRY USE

Initial Treatment: Use 2¼ oz. LONZA MILDEW PREVENTATIVE per a maximum total of 60 gallons (500 lbs.) of water and a maximum of 100 pounds of fabric (dry weight). Dilute the appropriate amount of LONZA MILDEW PREVENTATIVE in one to two gallons of water and then add this solution to the wash wheel at the beginning of the final rinse cycle. A minimum rinse cycle time of 8 minutes is required.

Repeat treatment: Follow Initial Treatment directions and re-treat fabric after each washing

PRESERVATION AGAINST MILDEW BY SOAKING

Use 2¼ oz. LONZA MILDEW PREVENTATIVE per a maximum total of 60 gallons (500 lbs.) of weter and a maximum of 100 pounds of fabric (dry weight). A minimum soaking time of 8 minutes is required.

LONZA MILDEW PREVENTATIVE is effective in all water temperatures.

LONZA MILDEW PREVENTATIVE EPA REG. NO. 6836-30 EPA STAMPED LABEL 3-1-04, DRAFT 12-11-09

PAGE 3 OF 4

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, 182 (2010)

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(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

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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.)

(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.

ACCEPTED with COMMENTS in EPA Letter Dated: MAR 2 2010 Under the Federal Insecticide,

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LONZA MILDEW PREVENTATIVE EPA REG. NO. 6836-30 EPA STAMPED LABEL 3-1-04, DRAFT 12-11-09