10836-30

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

03-01-2004

MAR - 1 2004

Mr. Robert Sloan Sr. Regulatory Services Associate Lonza Inc. 17-17 Route 208 Fair Lawn, NJ 07410

Subject: Lonza Mildew Preventative EPA Registration Number 6836-30 Application / letter Dated December 29, 2003 EPA Received Date December 30, 2003

Dear Mr. Sloan:

The following amendment, submitted in connection with registration the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment:

revise labeling per EPA letter dated 11/14/03

General Comments:

A stamped copy of the labeling accepted with conditions 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 or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerel

Veľma Nóble Product Manager (31) Regulatory Management Branch I Antimicrobials Division (7510C)

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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.

LONZA MILDEW PREVENTATIVE

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%

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)

> LONZA INC. 17-17 Route 208 Fair Lawn, New Jersey 07410

ACCEPTED MAR 2004

Inder The Federal Insecticide, Fungicide and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 68.36 ~ 30

LONZA MILDEW PREVENTATIVE EPA REG. NO. 6836-30 EPA DRAFT LABEL 12-30-03

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LONZA MILDEW PREVENTATIVE is based on a highlyactive, 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, <u>see Use-Directions</u>.

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 PRESERVATIVE 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 care.

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 PRESERVATIVE as directed.

COMMERCIAL AND INSTITUTIONAL LAUNDRY USE

Initial Treatment: Use 2¼ oz. LONZA MILDEW PRESERVATIVE 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 PRESERVATIVE 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 PRESERVATIVE per a maximum total of 60 gallons (500 lbs.) of water 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.

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(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

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

Pesticide Storage

Do not store on side. Avoid creasing or impacting of side walls.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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

(*Plastic containers*): Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities by burning. If burned, stay out of way of smoke.

(Metal Containers:) Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(Fiber drums and liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of liner and drum in a sanitary landfill or incinerate if allowed by State and local authorities. Do not reuse empty drum or liner.

ACCEPTED MAR 1 2004 Under The Federal Insecticide, Fungicide and Rodenticide Act, as amended, for the pesticide registered under PA Rez. No (O

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