U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	EPA Reg. Number: 6836-424	Date of Issuance: 11/27/19
NOTICE OF PESTICIDE: <u>X</u> Registration <u>Cunder FIFRA, as amended</u>	Term of Issuance: Conditional	
	Name of Pesticide Product: PROXEL® BZ – LONZA PRESERVATIVE	
Name and Address of Registrant (include ZIP Code): Stephanie H. Stephens Lonza, Inc. 412 Mount Kemble Avenue Suite 200S Morristown, NJ 07960		
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.		
On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.		
 This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions: 1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data. 		
Signature of Approving Official:	Date:	
Vaytryn V. WJontaguo	11/27/19	
Kathryn Montague, Acting Product Manager 33 Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs		

Registration Notice Conditional v.20150320

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- 2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Zinc pyrithione GDCI-088002-1483, -37923
 - b. 1,2-benzisothiazolin-3-one GDCI-012401-1087

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <u>http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division</u>

- 3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 6836-424."
- 4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/15/2019
- Alternate CSF 1 dated 02/15/2019

If you have any questions, please contact Jake McFarley by phone at (703) 347-0123, or via email at McFarley.Jake@epa.gov.

Enclosure: Master Label

PROXEL® BZ – LONZA PRESERVATIVE

ALTERNATE BRAND NAMES:

PROXEL® BZ - LONZA ANTIMICROBIAL

ACTIVE INGREDIENTS: Zinc 2-pyridinethiol-1-oxide.......8% 1,2-Benzisothiazolin-3-one......12% OTHER Ingredients......80% Total......100%



6836-424

EPA Reg. No.

KEEP OUT OF REACH OF CHILDREN

DANGER

[Note to Reviewer. The signal word for this product is "DANGER". The following components of this master label, at a minimum, will appear on the front panel of all distribution labels. If the distribution label has a single panel and multiple columns, these components will appear in the center column or in an immediately adjacent column: Product Brand Name, Ingredient Statement, Signal Word, Child Hazard Warning, First Aid Statement, Company Name and Address, EPA Registration Number, EPA Establishment Number.]

SEE [SIDE] [BACK] [RIGHT] [LEFT] PANEL FOR PRECAUTIONARY STATEMENTS

Net Weight [Enter Net Weight].

MANUFACTURED FOR/BY: Lonza, Inc. 412 Mount Kemble Avenue, Suite 200S Morristown, NJ 07960

Made in China, formulated in the UK.

EPA Reg. No. 6836-UEU EPA Est. No. [Enter EPA Establishement number]

PROXEL® is a registered trademark of Lonza, Inc.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear long-sleeved shirt and long pants, socks, shoes, goggles, or face shield, and chemical-resistant gloves made of any waterproof material. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

User Safety Requirements: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

User Recommendations:

- User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

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.

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 convulsions may be necessary. In case of emergency, for additional information call 1-800-654-6911.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, 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 AND CHEMICAL HAZARDS: Keep away from strong oxidizers.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Protect from frost. If frozen, allow to thaw and stir well before use.

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. Offer for recycling if available. Triple rinse container promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

[For containers > 5 gallons or 50 pounds] Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times

[For containers \leq 5 gallons or 50 pounds] Triple rinse as follows: Empty remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[For Totes/IBCs]

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. 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 Bulk Shipments and Transport Vehicles such as Portable Tanks, Tanker Trucks, Tank Trailers and Railcars] Emptied container retains vapor and product residue. Observe all precautions stated on this label until the container is cleaned, reconditioned or destroyed. Prior to refilling, inspect carefully for damage such as cracks, punctures, abrasions, and worn-out threads and closures. Clean thoroughly before reuse for transportation of a material of different composition or before retiring this transport vehicle from service. **DIRECTIONS FOR USE:** It is a violation of federal law to use this product in a manner inconsistent with its labeling.

This product is an effective preservative in most aqueous compositions. Typical applications, and the suggested range of concentrations on which trials can be based are:

NON-FOOD CONTACT USES:

Latices: Polymer latices based on acrylate, butadiene, PVA and styrene for various applications, add 0.025 - 0.20% of this product, or 0.25 – 2 gallons product per 1,000 gallons solution, based on total weight of product.

Paints and Stains: For in-can preservation, add 0.01 - 0.15% of this product, or 0.1 – 1.5 gallons product per 1,000 gallons solution, based on total weight of product.

Adhesives: Carboxymethylcellulose (CMC) and derivatives, animal glues, adhesives based on gelatins and latex, add 0.25 - 0.30% of this product, or 2.5 - 3 gallons product per 1,000 gallons solution, based on total weight of product.

Aqueous Mineral Slurries:

- titanium dioxide, calcium carbonate, and clay slurries
- buffing compounds, waxes and putties, abrasive compounds, polishes (not for use in California)

Add 0.05 - 0.35% of this product, or 0.5 – 3.5 gallons product per 1,000 gallons solution, based on total weight of product.

Tape joint compounds: Wallboard, spackling and drywall joint products, add 0.05 - 0.25% of this product, or 0.5 - 2.5 gallons product per 1,000 gallons solution, based on weight of product.

Pigment dispersions: Add 0.1 - 0.4%, or 1.0 - 4.0 gallons per 1,000 gallons solution, of this product based on weight of product.

General Recommendations: The concentration required to give protection depends on several factors. These include susceptibility of the system to microbiological degradation, the extent to which microorganism can gain access, the species involved, pH, temperature, and length of time for which protection is required. For protection against fungal attack, a concentration within the range of 0.025 - 0.4% of this product, or 0.25 – 4 gallons product per 1,000 gallons solution, is almost invariably sufficient.

*INDIRECT FOOD CONTACT USES:

To Control Growth of Bacteria and Fungi In Adhesives Used For Food Packaging: For food packaging adhesives, at use temperatures up to 120°F, and subject to Good Manufacturing Practices, including the conditions specified in 21 CFR 175.105 (a) and (b), add a dosage to a maximum of 4000 ppm of this product, or 4.0 lb. of this product per 1000 lbs. of food packaging adhesive, at a point where thorough mixing will take place.

To Control Growth of Bacteria and Fungi In Latex Emulsions or Aqueous Inorganic Slurries Used In the Manufacture of Food Contact Coated Paper:

To control the growth of bacteria and fungi in aqueous paper coatings and paper coatings components including latex, starch solutions, and mineral or pigment slurries (clay, kaolin clay, calcium carbonate, or titanium dioxide) at a dosage not to exceed 4000 ppm of this product, or 4.0 gallons of this product per 1000 gallons of solution, in the paper coatings components and not to exceed 1250 ppm of this product, or 1.25 gallons product per 1,000 gallons solution, in the paper coating formulation. Add this product at any point in the paper coating process.

Proxel® BZ – Lonza Preservative product licensing and patent notice: This product contains 1,2-Benzisothiazolin-3-one and zinc pyrithione and may be used in the preservation of industrial water based products against spoilage from bacteria, yeast and fungi in accordance with the label and processes, compositions and methods claimed in U.S. Patents 6,306,413 and European patent

Note: Text in [Square Brackets] are notes to the label reviewer. Text in {Curly Brackets} is optional. Proxel[®] BZ - Lonza Preservative EPA Reg. No.: 6836-UEU EPA Draft Label: 11-27-2019 0703726; and their other corresponding foreign patents. Purchase of this product from Lonza, Inc. gives the purchaser a nonexclusive license to use this product in the formulations claimed in the above-mentioned patents, and the royalty for this license is incorporated into the purchase price of the product.

*Not for Use in California

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