



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Antimicrobials Division (7510P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

6836-398

Date of Issuance:

11/25/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Proxel XL2- Lonza

Name and Address of Registrant (include ZIP Code):

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/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kathryn V. Montague, Team 33
 Regulatory Management Branch I
 Antimicrobials Division (7510P)

Date:

11/25/19

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. BIT (1,2-benzisothiazolin-3-one GDCI 098901-1466

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): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 6836-398.”
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 12/17/2018
- Alternate CSF 1 dated 12/17/2018

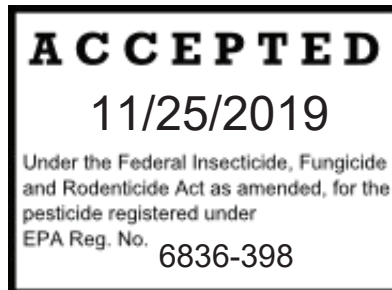
If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Enclosure: Approved label

PROXEL® XL2 – LONZA

ALTERNATE BRAND NAMES:

PROXEL® XL 2 – LONZA ANTIMICROBIAL
PROXEL® XL 2 – LONZA INDUSTRIAL MICROBIOSTAT
PROXEL® XL 2 – LONZA PRESERVATIVE



FOR INDUSTRIAL USE ONLY AS A MICROBIOSTAT PRESERVATIVE FOR AQUEOUS COMPOSITIONS SUCH AS LATICES, EMULSION PAINTS AND STAINS, OIL-IN-WATER EMULSIONS, PAINTS, WATER-BASED ADHESIVES, PAPER COATING COMPOSITIONS, CASEIN/ROSIN DISPERSIONS, TEXTILE SPIN-FINISH SOLUTIONS, PESTICIDE FORMULATIONS, AQUEOUS SLURRIES, TITANIUM DIOXIDE SLURRIES, TAPE JOINT COMPOUNDS, LEATHER PROCESSING SOLUTIONS, AND FOR THE PRESERVATION OF FRESH ANIMAL HIDES AND SKINS.

ACTIVE INGREDIENT:

1,2-benzisothiazolin-3-one 9%
Inert Ingredients 91%
Total..... 100%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

{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 ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

MANUFACTURED FOR:

Lonza, Inc.
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960

{Made in [Enter country of origin].}

PROXEL® is a registered trademark of Lonza, Inc.

Net Weight [Enter Net Weight]

EPA Reg. No. 6836-GOI
EPA Est. No. [Enter EPA Establishment Number]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Causes skin burns. Do not get in eyes, on skin or clothing. May be fatal if inhaled. Do not breathe vapor or spray mist. Harmful if swallowed or absorbed through the skin. Wear goggles or face shield, coveralls over long-sleeved shirt and long pants, chemical-resistant footwear and socks, and chemical-resistant gloves made of waterproof material. Wear a NIOSH approved respirator with an organic vapor (OV) cartridge with a combination R or P filter, A NIOSH approved respirator with an organic vapor (OV) cartridge with a combination N, R or P filter with NIOSH approval Label Review Manual Chapter 10: Worker Protection Labeling 10-13 with NIOSH approval number prefix TC – 84A; or a NIOSH approved gas mask with a canister with NIOSH approval number prefix TC – 14G; or a NIOSH approved powered air purifying respirator with organic vapor (OV) cartridge and combination HE filter with NIOSH approval number prefix TC – 23C. 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: 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. 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.

PHYSICAL AND CHEMICAL HAZARDS

Do not mix with oxidizing agents.

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 Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further 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.

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.

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: [For containers > 5 gallons] 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] 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 equal to or < 5 gallons] 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 ¼ 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:

Latices: Natural and synthetic latices based on acrylate, butadiene, PVA, styrene and other monomers, for use in various applications, e.g., wax, paint, floor polishes, synthetic rubber latices, add 0.10 - 0.30% of this product (based on total weight of product).

Emulsion paints and Stains: for in-can preservation, add 0.1 - 0.3% of this product (based on total weight of product).

Oil-in-water emulsions: "Spin finish" solutions for use in the textile industry. Cutting/rolling oils. Soluble oils (metal and engineering industries), add 0.1 - 0.3% (based on total weight of product).

Adhesives: Carboxymethylcellulose (CMC) and derivatives, animal glues, adhesives based on gelatins and latex, add 0.1 - 0.5% of this product (based on total weight of product).

Paper coating compositions: Rosin dispersions. Starch and casein based products. Add 0.1 - 0.3% of this product (based on total weight of product).

Pesticide formulations: For product preservation. For ultimate use-dilution protection. This product is exempt from tolerance under 40CFR180.920, materials exempted from the requirements of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only. Based on the current 180.920 limit of 0.1% BIT in formulations, use levels of up to 0.5% (5000 ppm) of this product are allowed, add 0.1 – 0.5% of this product (based on total weight of product).

Aqueous mineral slurries: Add 0.05 - 0.25% of this product (based on total weight of product).

Tape joint compounds: Add 0.16 - 0.5% of this product (based on total weight of product).

Inks: Add 0.10 - 0.25% of this product (based on total weight of product).

Preservation of Fresh Animal Hides and Skins: To preserve the integrity of fresh animal hides and skins prior to or during processing, use 26 fluid ounces to 5 gallons (2-48 lbs) of this product per 1000 pounds of hides or skins. Add the appropriate quantity of this product to the brine solution during the curing operation or treat hides or skins with an appropriately diluted aqueous solution during other portions of the processing operation. The specific use rate and contact time needed to control microbial attack will depend upon the degree of decomposition of the hides or skins prior to treatment. Leather Processing Solutions. Use this product at levels of 0.05 – 0.4% for the preservation of leather processing solutions.

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 bacterial attack, a concentration within the range of 0.04 - 0.7% of this product is almost invariably sufficient.

The control of mold growth, particularly on paste products of high solids content, may occasionally demand dosages above 0.5%.

In dilute fluid systems, spoilage is usually controlled with dosages not greater than 0.18%.