SOUTHER STATES	U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	EPA Reg. Number: 6836-421	Date of Issuance: 11/21/19	
NOTICE OF PESTICIDE: <u>X</u> Registration <u>Cunder FIFRA, as amended</u>		Term of Issuance:		
		Conditional		
		Name of Pesticide Product: Proxel Spektra – Lonza Preservative		
Name and Address of Re	egistrant (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 review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data. 				
Signature of Approving Official:		Date:		
Kathryn V. Montague, Acting Product Manager 33 Regulatory Management Branch I		11/21/19		
Antimicrobials D	-			
EPA Form 8570-6				

Registration Notice Conditional v.20150320

Page 2 of 2 EPA Reg. No. 6836-421 Decision No. 553715

- 2. You are required to comply with the data requirements described in the DCI identified below:
 - a. BIT (1,2-Benzisothiazol-3(2H)-One) GDCI-012401-1087
 - b. Sodium omadine or sodium, 2-pyridinethiol-1-oxide) GDCI-088004-1663

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. 6836-421."
- 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 02/14/2019
- Alternate CSF 1 dated 02/14/2019

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 SPEKTRA® - LONZA PRESERVATIVE

Active Ingredient:	
1,2-benzisothiazolin-3-one	2.0%
Sodium, 2-pyridinethiol-1-oxide	4.0%
Other Ingredients:	
Total	

A C C E P T E D 11/21/2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000, 404

^{g. №0.} 6836-421

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

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

[Made in [Enter country of origin]

EPA Reg. No. 6836-UER EPA Est. No. [Enter EPA Establishment Site] Net Weight [Enter Net Weight]

Proxel[®] is a registered trademark of Lonza, Inc.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear goggles or safety glasses, protective clothing and rubber gloves when handling this product. 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. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear protective eyewear (goggles, safety glasses or face shield), chemical-resistant gloves and protective clothing (long-sleeved shirt and long pants with socks and shoes).

USERS SAFETY REQUIREMENTS:

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

USER SAFETY INSTRUCTIONS:

Users must wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove personnel protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly.

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, or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 am to 12 pm PST, or at http://npic.orst.edu.

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 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 further 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.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment advice. In case of emergency or for additional information call 1-800-654-6911.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish and wildlife. 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.

STORAGE & DISPOSAL

Do not contaminate water, food, or feed by storage or disposal or cleaning of equipment. **PESTICIDE STORAGE:** Store in a cool place. Protect from excessive heat.

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 containers}

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 procedures approved by state and local authorities.

{For containers >5 gallons or 50 lbs net weight}

Triple rinse as follows: Fill container ¼ full with water. 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. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times.

{For containers < 5 gallons}:

Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Drain for 10 seconds after the flow begins to drip. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat procedure two more times.

{Refillable containers, all sizes}

Refillable container. Refill this container with pesticide only. Do not use this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

[BULK BAG OR SUPERSACK:] Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available, or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. ["Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)]

DIRECTIONS FOR USE:

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

Do not apply this product in a way that will contact workers or other persons.

PROXEL SPEKTRA® - LONZA PRESERVATIVE is typically effective when applied at the suggested concentrations shown. All concentrations are based on the total formulation weight. Add PROXEL SPEKTRA® - LONZA PRESERVATIVE at the end of the manufacturing cycle, at a point in the process where thorough mixing of PROXEL SPEKTRA® - LONZA PRESERVATIVE into the preserved product will occur.

Paints, Stains, and Coatings

PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in water based coatings, (including process wash solutions) including coatings for architectural and industrial materials and for non-food contact paper and cellulosic materials.

{*} Latex, Polymer Emulsions or Solutions

PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for the control of bacteria and fungi in the manufacture and storage of synthetic and natural polymer lattices (including process wash solutions) and polymer solutions including all types of latex binders for coatings use and polymer based rheology modifiers including biopolymers intended for industrial use such as xanthan gum, gum arabic, guar gum, protein derived polymers, starches, and casein derived polymers including lattices for non-food contact paper and paperboard.

()* Building Products and Mineral Slurries

PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in water based building materials including: concrete admixtures, joint compound, spackle, caulk, sealant, stucco, grout, wood fillers, putties and waxes, buffing and abrasive compounds, glazing compounds, polishes, calcium carbonate slurry, titanium dioxide slurry, and other non-food contact mineral slurries.

{*} Adhesives and Tackifiers

PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in water based adhesives and tackifiers including adhesives based on natural rubber or synthetic lattices.

()* Pigment Cake, Pigment Dispersions, Fountain Solutions, Dyes, and Inks 0.25 – 2.5% PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in water based inks, fountain solutions, pigment dispersions or colorants, and pigment press cake. PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for water based printing inks such as flexographic, gravure, screen, and ink jet types. PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in ink jet components such as resins, plasticizers, water soluble dyes, pigments, gelling agents, surfactants, and thickeners.

Up to 150 lb PROXEL SPEKTRA® - LONZA PRESERVATIVE per 1000 lb of concentrate may be added to concentrates so long as the final product contains not more than 750 ppm active ingredients (a dilution of 20x).

0.1 - 2.0%

0.2 - 2.0%

0.1 - 1.0%

0.1 - 1.0%

{*} Oil-in-Water Fluids

0.063 - 0.625%PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in water based oil-in-water fluids such as metalworking, cutting, cooling, and lubricating fluids. To inhibit bacterial and fungal growth add an initial dose of 630 ppm up to 6250 ppm of PROXEL SPEKTRA® -LONZA PRESERVATIVE to the solution by pouring from the container and subsequent maintenance doses of 630 ppm up to 6250 ppm every 7- 10 days or as needed.

*{***}* Oil-in-Water Concentrates

PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in water based oil-in-water concentrates such as metalworking, cutting, cooling, and lubricating fluid concentrates. To inhibit bacterial and fungal growth add an initial dose of 630 ppm up to 6250 ppm of Proxel Spektra Preservative. The amount required in the concentrate will depend on the end use dilution. For example: If the desired level of PROXEL SPEKTRA® - LONZA PRESERVATIVE is 6250 ppm and the end use dilution of the fluid is 5%, then a 12.5% concentration of PROXEL SPEKTRA® - LONZA PRESERVATIVE is required in the concentrate.

{}* Textile Auxiliaries and Fiber Lubricants

PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in liquid textile auxiliaries for woven or non-woven products (such as fiber lubricants, spin finishes, sizes, dyestuffs, textile printing inks, dispersants, thickeners, dye fixatives), and in textile coatings.

*{**} Household, Consumer, Industrial, and Janitorial Products 0.1 - 0.8%PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended for control of bacteria and fungi in cleaning products such as surface cleaners, carpet and fabric cleaners, floor cleaners, air fresheners/deodorizers, laundry detergents, laundry rinse additives, stain removers, and other similar cleaners.

PROXEL SPEKTRA® - LONZA PRESERVATIVE may be used to preserve liquid and solid formulations of these products or it may be used to preserve formulations offered as semi-solid gels, polishes, or waxes, or as pre-moistened, wipes, mops, or sponges.

{*} Preservation of Fresh Animal Hides and Skins

PROXEL SPEKTRA® - LONZA PRESERVATIVE is used to prevent the bacterial or fungal degradation of hides and skins. Application level is dependent on the type of hide or leather to be protected, the length of protection desired and the presence of other constituents in the processing formula. The optimum addition should be determined by trial for each individual application. For soaking raw hides this product should be added to the water to be used for soaking. For treating hides cured with dry salt, this product should be applied to the hides or should be mixed with the salt before it is applied to the hides. This product can be used for the protection of wet leather stock such as pickled, chrome, chrome alternative, metal free, and vegetable tanned leathers from mold and mildew during in-tannery wet processing and for the protection of wet-blue during long storage and transportation times. Treatment rates should be calculated based on the wet white weight or wet blue weight, and compatibility with chrome solutions or other treatment chemicals should be confirmed prior to trial.

{}* In-Container Preservative

PROXEL SPEKTRA® - LONZA PRESERVATIVE is recommended as an in-container preservative for control of bacteria and fungi in aqueous products, aqueous emulsions, and dispersions including; diagnostic reagents, surface preparation compounds, nutrient solutions, silicone emulsions, and foam control products.

{*Not for use in California}

Proxel Spektra® – Lonza Preservative EPA Reg. No.: 6836-UER EPA Draft Label: 2019-11-05

0.1 - 0.625%

0.1 - 5.0%

0.1 - 0.6%