



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 4, 2019

Jennifer DePietro
Regulatory Affairs Associate
Lonza Inc.
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960

Subject: Label Amendment – Minor Label Changes
Product Name: BIO-QUAT 80-28 For Manufacturing Use Only
EPA Registration Number: 6836-162
Application Date: November 14, 2018
Decision Number: 546549

Dear Ms. DePietro:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

BIO-QUAT® 80-28

For Manufacturing Use Only

For Use By Manufacturers Only In Formulating Antimicrobial Products For The Uses Indicated On The Label

Active Ingredients:

Alkyl (C ₁₄ -58%, C ₁₆ -28%, C ₁₂ -14%) Dimethyl Benzyl Ammonium Chloride.....	40.0%
Other Ingredients.....	20.0%
Total.....	100.0%

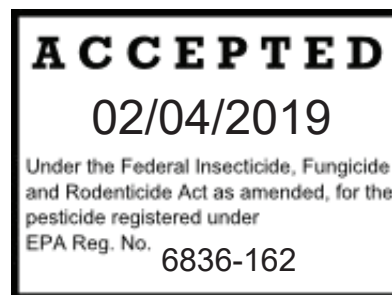
KEEP OUT OF REACH OF CHILDREN

DANGER

EPA Reg. No. 6836-162
EPA Est. # XXXX-XX-XX
Net Contents: *(as indicated on container)*

[DOT Symbols]
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

Lonza Inc.
412 Mt. Kemble Ave., Suite 200S
Morristown, NJ 07960



Emergency Contact Number: (_____)

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. May be fatal if inhaled. Do not breathe vapor. Wear a minimum of a filtering face piece NIOSH approved respirator (TC-84A) with any N filter. Higher level respirators that are NIOSH approved for particulates can also be used. Wear goggles or face shield, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing 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. 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.

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.

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.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. 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.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. DO NOT USE OR STORE NEAR HEAT OR OPEN FLAME

DIRECTIONS FOR USE

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

This product is a concentrate for formulating purposes only. This product for formulation into antimicrobial products for use in/on Agricultural premises and equipment, Food Handling/storage establishment premises and equipment, Commercial, institutional and industrial premises and equipment, Residential and public access premises, Medical Premises and equipment, Industrial processes and water systems, Wood preservatives and Swimming Pools. Formulators using this product are responsible for providing data for the EPA registration of their formulated products. This product may be used to formulate products for specific use(s) not listed on this label if the formulator or primary registrant has complied with U.S. EPA data requirements regarding the support of such use(s).

NOTE: This product should not be used or compounded with any reducing or oxidizing agents (such as calcium hypochlorite, solid perchlorate, or nitric acid) since such mixtures may be explosive. Do not use in conjunction with soap or any anionic wetting agent.

STORAGE AND DISPOSAL

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. Do not store on side.

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 HANDLING

(For Nonrefillable Plastic containers \leq 5 gallons)

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For Nonrefillable Plastic containers $>$ 5 gallons but \leq 100 gallons)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. 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. 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. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For Nonrefillable Containers $>$ 100 gallons)

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. To clean the container, empty the remaining contents from this container into application equipment or a 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. Return to point of sale or offer for recycling if available or reconditioning if appropriate.