



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 16, 2016

Mr. Jonathan Walsh
Regulatory Assurance Specialist for,
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Label Amendment – To add medical use sites to the Directions for Use
Product Name: Lonzabac 12
EPA Registration Number: 6836-283
Application Date: September 16, 2016
Decision Number: 521792

Dear Mr. Walsh:

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.

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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 with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,



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

Enclosure

ACCEPTED

11/10/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 6836-283

LONZABAC 12

For Manufacturing-Use Only

ACTIVE INGREDIENT:
Bis (3-aminopropyl) dodecylamine.....91.40%
INERT INGREDIENTS:.....8.60%
TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

EPA Reg. No. 6836-283
EPA Est. No. (insert EPA Est. No.)

{DOT Symbols and language}

Net Weight _____
LONZA INC. 90 Boroline Road, Allendale, NJ 07401

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Do not breathe vapor. Wear a respirator with an organic removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles, face shield, or safety glasses, protective clothing and chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash clothing before reuse.

DIRECTIONS FOR USE

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

For formulation into antimicrobial/disinfectant products for use on hard, non-porous non-food contact surfaces in: businesses and office buildings, hotels, motels, correctional facilities, athletic facilities, schools, barber shops, locker rooms, non-food areas of food-processing plants and restaurants, bars and cafeterias, convenience rooms, public restrooms, animal laboratories, pet shops, factories, and medical facilities including; hospitals, clinics, nursing homes and other medical offices.

Lonzabac 12 can also be used to formulate products used to control antimicrobial contamination in oil field water flood systems and metalworking fluids.

Formulators using this product are responsible for providing data for the EPA registration of their formulated products.

{Note to reviewer: For Nonrefillable Containers for industrial uses. Chapter 13, Table 6 of the Label Review Manual states that for "All products in containers that could be burned," the registrant has the option to "Remain silent on burning;" therefore, no incineration language is provided for plastic containers.}

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store upright in original container and place in a locked storage area inaccessible to children. Do not reuse empty container.

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 Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

{Note to reviewer: This Container Statement will be used only for containers 5 gallons or less:}

Container Disposal: Nonrefillable container. Do not reuse or refill this container.

{Plastic and Metal Containers:} Triple rinse as follows: Empty the 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. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

{For metal containers only:} DO NOT cut or weld metal containers.

{Bag in Box Containers:} Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: This Container Statement will be used for containers over 5 gallons:}

FIRST AID	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
If On Skin Or Clothing:	<ul style="list-style-type: none"> 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 In Eyes:	<ul style="list-style-type: none"> 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. Call a poison control center or doctor for treatment advice.
If Inhaled:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, Call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none"> 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.	

ENVIRONMENTAL HAZARDS

This product is highly toxic to birds, fish and aquatic invertebrates. 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.

Container Disposal: Nonrefillable container. Do not reuse or refill this container.

{Plastic and Metal Containers:} Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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 or reconditioning. If not available, puncture and dispose in sanitary landfill. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

{For metal containers only:} DO NOT cut or weld metal containers.

{Bag in Box Containers:} Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Fiber drums with liners:} Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.