



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

EPA Reg. Number:

6836-438

Date of Issuance:

12/17/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Densil LE1 Antimicrobial

Name and Address of Registrant (include ZIP Code):

Leesha N. Square
 Regulatory Specialist
 Lonza Inc.
 412 Mt. 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:

John Hebert, Chief
 Regulatory Management Branch 1
 Antimicrobials Division (7510P)
 Office of Pesticide Programs

Date:

12/17/19

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCI identified below:

- a. 3-Iodo-2-propynylbutylcarbamate GDCI-107801-1341
- b. n-butyl-1, 2-benzisothiazolin-3-one GDCI-098951-1626

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. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 6836-438.”
5. 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 06/24/2019
- Alternate CSF 1 dated 06/24/2019
- Alternate CSF 2 dated 06/24/2019
- Alternate CSF 3 dated 06/24/2019
- Alternate CSF 4 dated 10/29/2019

- Alternate CSF 5 dated 10/29/2019

If you have any questions, please contact Jake McFarley by phone at (703) 347-0213, or via email at McFarley.Jake@epa.gov.

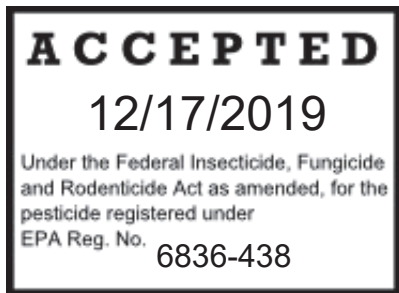
Enclosure: Master Label

Note to Reviewer: Text in [Square Brackets] are notes to the label reviewer. Text in {curly Brackets} is optional.

Densil® LE1 Antimicrobial

Active Ingredient:

3-Iodo-2-propynylbutylcarbamate.....	5.0%
n-butyl-1, 2-benzisothiazolin-3-one.....	5.0%
Other Ingredients:	<u>90.0%</u>
Total	100.0%



KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

[Note to Reviewer: For multiple panel labels.]

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

MANUFACTURED FOR/BY:

LONZA INC.
412 Mt. Kemble Avenue
Suite 200S
US – 07960 Morristown

[Made in [Enter country of origin]]

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

Densil® is a registered trademark of Arch UK Biocides Limited

[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 (foreword facing) panel of all multiple-panel 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.]

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if swallowed. Harmful if inhaled. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). 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. Avoid breathing spray mist. Wear long sleeved shirt, and long pants, socks, shoes and chemical- resistant gloves.

Prolonged or frequently repeated skin contact may cause allergic reactions 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 exist, 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.

IF ON SKIN: 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 further treatment advice.

Note to Physician: Causes irreversible eye damage. Probable mucosal damage may contraindicate the use of gastric lavage

Have the product container or label with you when you call a Poison Control Center or doctor, or when going for treatment. 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.

Note to Reviewer: Text in [Square Brackets] are notes to the label reviewer. Text in {curly Brackets} is optional.

[“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.

METALWORKING FLUIDS

Fluid Concentrate

This product should be added to metalworking fluid concentrates at a level that ensures the final use dilution fluid will contain 500 to 3900 parts per million (ppm) of product (50 to 390 ppm active ingredient).

Use Dilution Fluid

Note that grossly contaminated systems may require mechanical removal of fungal masses, and cleaning of the system before biocide treatment is begun.

Initial Dose: For noticeably fouled systems, add 4.25 to 33.3 lbs. (64 to 500 fl. oz.) of this product per 1000 gallons of fluid. This will generate a concentration of 25 ppm n-butyl-1,2-benzisothiazolinone and 25 ppm 3-Iodo-2-propynylbutylcarbamate to 195 ppm n-butyl-1,2-benzisothiazolinone and 195 ppm 3-Iodo-2-propynylbutylcarbamate.

Subsequent Dose: For maintenance of a clean system, add 0.81 to 5.3 lbs. (12.2 to 79.5 fl.oz.) of this product per 1000 gallons of fluid on a periodic basis to maintain microbial control. This quantity will generate a fungicide concentration of 10 to 60 ppm active ingredient. The frequency of maintenance dosing will be affected by the amount of fluid lost to drag out and other displacements, but also by the severity of the contamination, by the system design, by the effectiveness of system filtration, and by other system variables.

{*} CONSTRUCTION MATERIALS

Many building construction materials support the growth of a wide range of bacteria, fungi and algae. The uncontrolled growth of these microorganisms either in the wet or dry stage can lead to aesthetic problems such as odor or surface staining or it can lead to premature product failure.

This product has been found to be an effective wet state preservative at concentrations of 1.0 lb – 10.0 lb per 1000 lb of treated product (0.1% to 1.0%), and an effective dry state preservative at concentrations of 10 lb – 21.0 lb per 1000 lb of treated product (1.0% to 2.1%), based on the total weight of the substrate. Example end use applications are shown below:

For preservation of emulsions, dispersions, slurries, and thickeners including latex emulsions, urethane dispersions, mineral or pigment slurries (such as clay, kaolin, calcium carbonate, and titanium dioxide). For preservation of pulp and paper slurries and for preservation of paper coating compositions, including starch preparations. Add 0.1 – 1.0% of this product. Not for use in food contact paper products or paper coatings.

For preservation of adhesives, tape joint compounds, spackle, stucco, grout, glazing compounds, fillers, sealants, caulks, and weather stripping. Add 1.0 – 2.1% of this product. Not for use in food contact adhesives.

For preservation of manufactured paper and paperboard products such as insulation facing, wallboard facing, stationeries, and paper packaging. Add 1.0 – 2.1% of this product. Not for use in food contact paper products.

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For preservation of composites, gypsum, perlite, plaster-like or mineral and cellulose materials. For preservation of ceiling tiles, partitions, dry wall and wallboard. Add 1.0 – 2.1% of this product.

For preservation of coatings and stains: exterior and interior preservation of architectural and industrial coatings and stains. Add 1.0 – 2.1% of this product. Not for marine use.

{*} PLASTICS:

Many plastics are considered to be resistant to microbial attack, but there are significant exceptions that merit preventative action by the use of antimicrobial additive. Plasticized PVC, polyurethane and silicones are particularly susceptible. The biodeterioration of products based on these types of plastics can be a serious problem for manufacturers. Failure to add the proper amount of antimicrobial additive can lead to premature product failure due to loss of mechanical strength, flexibility or adhesive strength. Also, adverse aesthetic problems such as musty odor, permanent staining or microbial surface growth can lead to customer complaints.

Densil® LE1 Antimicrobial is effective against the microbes which degrade plastics (and plastic additives) or natural rubber and can increase the useful life of articles made from these materials. Densil® LE1 Antimicrobial is effective in most plastic compositions and can be used to preserve natural rubber and such plastics as PVC, polyurethane, silicone, acrylics, and others to produce articles such as; coated fabric (e.g. ski wear, raincoats, tents, seat covers), floor coverings, underlay and mats, vinyl wall coverings, tarpaulins and awnings, roofing membranes, synthetic leather (e.g. sneakers and training shoe uppers), swimming pool liners, ornamental pond liners, appliance gaskets (e.g. washers, refrigerator), shoe soles, mid-soles and outers, sealants, sealers, coatings, caulks, weather stripping and non-food contact adhesives, pet toys and general household items (shower curtains, bath mats, sink drain mats, rubber or plastic coated wire shelving and dish drainers), auto parts (e.g. landau tops, door seals, shock absorbers), foam (e.g. seat cushions, gaskets, insulation), tubing (e.g. marine hose and sleeving), electrical and pipe wrap, furniture (e.g. outdoor, leisure, water bed liners, cushions, covered foam mattress padding, covered foam pillow cushions). Do not use this product to treat drinking water contact items or toys.

Use levels of 4.0 lb – 60.0 lb per 1000 lb of treated product (0.4 – 6.0%) by weight of the plastic are generally adequate. This product should be dispersed in the plasticizer or color concentrate before it is incorporated into the resin to ensure a uniform distribution. Use of this product is not recommended if the heat of processing is above 350°F for prolonged periods, nor must it be used in a plastic that will be in contact with food or medical device applications.

For example to inhibit the growth of mildew on a plastic such as polyurethane boat seat cushion intended for a non-food area add 0.4% (4 lbs. of this product/1000 lbs. of polyurethane formulation) of this product to the polyurethane formulation.

{*Not for use in California}