#### U.S. ENVIRONMENTAL PROTECTION AGENCY

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

6836-403

Date of Issuance:

EPA Reg. Number:

6/6/19

Term of Issuance:

Conditional

Name of Pesticide Product:

DENSIL DG20 - LONZA **ANTIMICROBIAL** 

NOTICE OF PESTICIDE:

X Registration Reregistration (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Lonza, Inc. 412 Mount Kemble Avenue, Suite 2005 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/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
	6/6/19
Zeno Bain, Product Manager 33	
Regulatory Management Branch I	
Antimicrobials Division (7510P)	
Office of Pesticide Programs	

- 2. You are required to comply with the data requirements described in the DCI Order identified below:
  - a. GDCI 098951-1626 EPA-HQ-OPP-2015-0736

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

- 3. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 6836-403."
- 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 January 25, 2019
- Alternate CSF #1 January 25, 2019
- Alternate CSF #2 January 25, 2019

If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov.

## **DENSIL® DG 20 - LONZA ANTIMICROBIAL**

For the Preservation of Metalworking Fluids, <sup>1</sup>Coatings, and <sup>1</sup>Other Construction Materials

#### ACTIVE INGREDIENT:

N-BUTYL-1, 2-BENZISOTHIAZOLIN-3-ONE	20%
INERT INGREDIENTS:	80%
TOTAL INGREDIENTS	100%

<sup>1</sup>Coatings and Other Construction Materials not approved for use in California

## KEEP OUT OF REACH OF CHILDREN

## **DANGER**

## ACCEPTED

Jun 06, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 6836-403

#### **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. 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 INHALED:** 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 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 by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

#### **MEDICAL EMERGENCY INFORMATION CENTER 1-800-654-6911**

**NOTE TO PHYSICIAN:** Possible mucosal damage may contraindicate the use of gastric lavage following ingestion.

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

SEE ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

EPA Reg. No. 6836-NEW49
EPA Est. No. [Enter EPA Establishment number]
{Made in [Enter country of origin].}

For information on spills, call 1-800-654-6911

Net Weight: [Enter Net Weight]

Manufactured for: Lonza, Inc.. 412 MOUNT KEMBLE AVENUE, SUITE 200S MORRISTOWN, NJ 07960

DENSIL® is a registered trademark of Lonza, Inc.

Densil® DG 20 – Lonza Antimicrobial EPA Reg. No.: 6836-NEW49 EPA Draft Label: 2019-01-04

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER.

Corrosive. Causes irreversible eye damage and skin burns. Maybe fatal if inhaled. Harmful if swallowed or absorbed by skin. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear such as googles, face shield, or safety glasses. Coveralls worn over long-sleeve shirt and long pants, socks, chemical-resistant footwear, chemical-resistant gloves (Barrier Laminate, or Butyl Rubber, or Neoprene Rubber, or Polyvinyl Chloride (PVC), or Viton, selection Category C). Wear a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter with NIOSH-approval number prefix TC-84A. 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.

#### PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear: coveralls or long-sleeved shirt and long pants, chemical resistant footwear and socks, goggles or face shield, chemicals-resistant gloves (such as: Barrier Laminate or Viton)

**ENVIRONMENTAL HAZARDS:** This product 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 the 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. Do not contaminate water by cleaning of equipment or disposal of wastes.

### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

#### **PESTICIDE STORAGE:**

Protect from frost. DO NOT FREEZE. If frozen, thaw and stir well before use.

#### 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:

Non-refillable 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 greater than 5 gallons}**\* Triple rinse as follows: Empty 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.

**{For containers less than or equal to 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

Densil® DG 20 – Lonza Antimicrobial EPA Reg. No.: 6836-NEW49 EPA Draft Label: 2019-01-04 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.

## PRECAUTIONARY STATEMENTS ON THE OPERATION OF METALWORKING EQUIPMENT WITH MWF CONTAINING DENSIL® DG 20 - LONZA ANTIMICROBIAL

For use in closed metalworking and delivery systems only. Do not permit contact with mixer/loaders or machinists. This product may be used ONLY in enclosed metalworking systems with local exhaust ventilation.

This product may NOT be used to preserve metalworking fluids intended for use in machining operations which are not enclosed, even when such operations do not generate significant MWF aerosol. In cases where a central sump is used, this product may NOT be used as a post additive treatment for the metalworking fluid unless all machining operations using this fluid are enclosed, even when the unenclosed equipment is not actively in use.

Do not use this product to treat metalworking fluids that will be resold for use in non-enclosed metal cutting systems.

#### Fluid Concentrate

This product should be added to metalworking fluid concentrates at a level that ensures the final use dilution fluid will contain 125 to 1000 parts per million (ppm) of product (25 to 200 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 1.06 to 8.87 lbs. (15.8 to 125.1 fl. oz.) of this product per 1000 gallons of fluid. This will generate a concentration of 25 to 200 ppm active agent.

Subsequent Dose: For maintenance of a clean system, add 0.2 to 1.31 lbs. (2.93 to 19.4 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 5 to 30 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.

#### <sup>1</sup>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 0.05% to 0.25%, and an effective dry state preservative at concentrations of 0.36% to 0.54%, 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 0.05-0.25% 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 0.36 - 0.54% 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 0.36 - 0.54% of this product. Not for use in food contact paper products.

For preservation of composites, gypsum, perlite, plaster-like or mineral and cellulose materials. For preservation of ceiling tiles, partitions, dry wall and wallboard. Add 0.36 – 0.54% of this product.

For preservation of coatings. Add 0.36 – 0.54% of this product. Not for marine use.

<sup>1</sup>Coatings and Other Construction Materials not approved for use in California.

#### **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® DG 20 - Lonza 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® DG 20 - Lonza 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

Densil® DG 20 – Lonza Antimicrobial EPA Reg. No.: 6836-NEW49 EPA Draft Label: 2019-01-04 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 food/feed or drinking water contact items or toys.

Densil® DG 20 – Lonza Antimicrobial has been found to be an effective polymer preservative at concentrations of 0.07% to 2.25% based on the total weight of the substrate. Typical range of concentrations on which trials can be based are:

APPLICATION % Densil® DG 20 – Lonza Antimicrobial (based on total weight of final product)

 Plasticized PVC
 0.15 to 2.48%

 Polyurethane
 0.248 to 2.48%

 Silicones
 0.248 to 4.95%

 Polyesters
 0.248 to 4.95%

 Polyolefins
 0.248 to 4.95%

 Acrylics
 0.248 to 4.95%

 Synthetic elastomers: such as
 0.15 to 4.95%

butadiene-styrene, styrene-Isoprene and acrylonitrile-

Butadiene-styrene

Natural latex rubber 0.15 to 2.48%

The concentration required to give protection depends on several factors. These include the susceptibility of the system to microbiological degradation, the extent to which micro-organisms can gain access, the species involved, pH, temperature, moisture and length of time for which protection is required.

#### INCORPORATION OF DENSIL® DG 20 - LONZA ANTIMICROBIAL INTO POLYMERS

Do not use for any application involving direct or indirect food contact.

PVC plastisols: For addition to PVC plastisols Densil® DG 20 – Lonza Antimicrobial liquid may be added along with the other additives. Use levels should be calculated based upon the total weight of the formulation.

**Cross Linked Polyurethane:** For addition to cross linked polyurethane Densil® DG 20 - Lonza Antimicrobial liquid should be added to the polyol at a concentration that will yield the desired use level in the final product after reaction with the isocyanate component. Densil® DG20 – Lonza Antimicrobial may also be incorporated at an injection port of a reaction injection molding (RIM) machine.

**Melt Processed Polymers:** For addition to melt processed polymers (PVC, thermoplastic polyurethane, synthetic elastomers and thermoplastic acrylics etc.) Densil® DG 20 - Lonza Antimicrobial liquid may be metered into the melt to yield the desired end use concentration. For example at the injection point in an extrusion system. Alternatively, Densil® DG 20 - Lonza Antimicrobial liquid may be made into a concentrated chip (as above at up to 40% Densil® DG 20 - Lonza Antimicrobial) and these chips blended with non-preserved chips in the users plant to yield the desired end use concentration upon subsequent melt processing. For thermoplastic polyurethane, concentrated granules may also be produced by absorbing Densil® DG 20 - Lonza Antimicrobial liquid to granules through shear mixing (up to 40% Densil® DG 20 - Lonza Antimicrobial). These can be blended with non-preserved polymer chips in the users plant to the desired use concentration and then further heat processed (i.e. via extrusion).

[Note to reviewer: Only one of the following 2 paragraphs will be used.]

[1.] PVC: This product may be added to the mixed liquid components or added to concentrate(s) that will be added to a blend of PVC resin and solids, shear mixed until a dry blend is achieved and then processed through extrusion, calendering, molding or other system. The concentrate must be used in proportion to untreated plastic and other inputs in the fabrication of plastic articles entering commerce so that the final concentration of active ingredient does not exceed the application rate range (0.03-0.5%) specified for the various plasticized PVC articles to be preserved.

[2.] PVC: This product may be added to the mixed liquid components or added to concentrate(s) that will be further processed to manufacture PVC articles or added to a blend of PVC resin and solids, shear mixed until a dry blend is achieved and then processed through extrusion, calendering, molding of other system. The concentrate must be used in proportion to untreated plastic and other inputs in the fabrication of plastic articles entering commerce so that the final concentration of active ingredient does not exceed the application rate range (0.03-0.5%) specified for the various plasticized PVC articles to be preserved.

**Acrylics:** In addition to the above, Densil® DG 20 Antimicrobial liquid can be added to the liquid monomers before polymerization, at levels to yield the desired use level in the final product after polymerization.

**Silicone:** For silicone sealants, the Densil® DG 20 Antimicrobial liquid may be added to the silicone oil before processing, or to the manufacturing vessel before packing off.

Natural Rubber: Densil® DG 20 Antimicrobial can be added to the latex.

The Arch Technical Service Group can provide additional guidance on the proper use of Densil® DG 20 Antimicrobial.

<sup>1</sup>Not approved for use in California