



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

EPA Reg. Number:

6836-435

Date of Issuance:

9/20/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Zinc Omadine FPS Aqueous
Dispersion – Lonza Industrial
Bactericide & Fungicide

Name and Address of Registrant (include ZIP Code):

Stephanie Stephens
Authorized Representative
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/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Date:

9/20/19

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Zinc pyriithione GDCI-088002-1483

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. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 6836-435.”
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 05/17/2019

If you have any questions, please contact Michael Varco by phone at 703-347-0403, or via email at Varco.Michael@epa.gov.

Enclosure

ZINC OMADINE® FPS AQUEOUS DISPERSION - LONZA INDUSTRIAL BACTERICIDE & FUNGICIDE

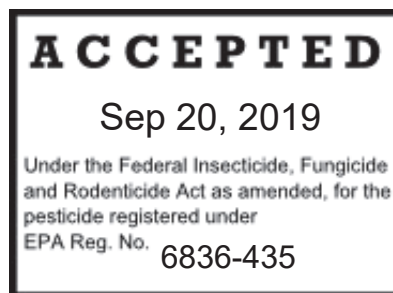
ALTERNATE BRAND NAMES:

MICROKILL™ 48% DISPERSION - LONZA INDUSTRIAL MICROBIOSTAT
REPUTEX 48 - LONZA ANTIMICROBIAL
ZINC OMADINE® 48% AQUEOUS DISPERSION – LONZA INDUSTRIAL MICROBIOSTAT
ZINC OMADINE® 48% AQUEOUS DISPERSION - LONZA
ZINC OMADINE® 48% DISPERSION - LONZA ANTIMICROBIAL
ZINC OMADINE® 48% DISPERSION FPS - LONZA
ZINC OMADINE® 48% DISPERSION FPS- LONZA INDUSTRIAL
ZINC OMADINE® 48% DISPERSION - LONZA INDUSTRIAL MICROBIOSTAT
ZINC OMADINE® 48% FPS - LONZA (INDUSTRIAL GRADE)
ZINC OMADINE® 48% FPS - LONZA INDUSTRIAL
ZINC OMADINE® 48% FPS - LONZA INDUSTRIAL GRADE
ZINC OMADINE® FPS - LONZA ANTIMICROBIAL
ZINC OMADINE® FPS - LONZA FUNGICIDE
ZINC OMADINE® FPS - LONZA GECT INDUSTRIAL BACTERICIDE & FUNGICIDE
ZINC OMADINE® FPS - LONZA INDUSTRIAL

ACTIVE INGREDIENT:

Zinc, 2-pyridinethiol-1-oxide.....48%
OTHER Ingredients..... 52%
Total.....100%

**KEEP OUT OF REACH OF CHILDREN
DANGER**



[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 ADDITIONAL PRECAUTIONARY STATEMENTS.

Net Weight: [Enter Net Weight].

MANUFACTURED FOR/BY:

Lonza, Inc.
412 Mount Kemble Avenue, Suite 200S

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

Zinc Omadine® FPS Aqueous Dispersion - Lonza Industrial Bactericide & Fungicide
EPA Reg. No.: 6836-UGL
EPA Draft Label: 2019-09-09

Morristown, NJ 07960

{Made in [Enter country of origin].}

EPA Reg. No. 6836-UGL

EPA Est. No. [Enter EPA Establishment number]

OMADINE® is a registered trademark of Lonza, Inc.

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PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER: Corrosive. Causes irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Harmful if inhaled. Do not breathe spray mists. Users must wear protective eyewear (goggles, safety glasses, or face shield), long sleeved shirt and long pants, socks, chemical resistant gloves and chemical resistant footwear. Users must wear a fit tested, NIOSH approved full face respirator equipped with a combination organic vapor/P-100 prefilter. When mixing and loading, or cleaning equipment, wear a chemical resistant apron. 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.

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 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 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, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further treatment advice.

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.

In case of emergency, for additional information call 1-800-654-6911.

CHEMICAL HAZARDS

Do not store or mix with strong oxidizing agents or strong (concentrated) acids. In case of contamination do not reseal container. If possible, isolate container in open or well-ventilated area. Fumes caused by contamination may be hazardous.

ENVIRONMENTAL HAZARD

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, 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.

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STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed when not in use. Do not store above 130°F. Do not store with strong oxidizing agents or strong (concentrated) acids.

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 container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration, or by other procedures approved by state and local authorities.

[For containers > 5 gallons] 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.

[For containers ≤ 5 gallons] 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.

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DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. We recommend that users contact Lonza, Inc. Technical Service for formulation assistance.

Overview: A minimum cost effective use level recommendation can only be established through testing of a specific formulation intended for use in a specific application. Formulations differ in their composition and as a result, of their susceptibility to microbial attack. Conditions of use and the performance expectations differ from product to product. A warranted high performance preserved product, for example, that is under consideration for use in severe tropical environments, is likely to need a high dose of biocide. Testing at biocide use levels would be recommended at 3000, 4000 and 5000 ppm. As the product adds cost to the formulation and as performance requirements need to be met, laboratory and field tests are conducted to establish the antimicrobial performance of this product. An unwarranted preserved product that is not intended for use in severe environments would likely need a lower dose. Again, a recommendation would be made for testing at lower concentrations based on formulation, performance and cost considerations.

NON-FOOD CONTACT USES:

TEXTILES:

This product will control the growth odor causing microorganisms on textiles made of natural and synthetic fibers such as polyester and blends.

Apply this product in the following applications such that the finished product contains 0.14 to 0.71% by weight of this product.

The following are examples of products (substrates) suitable for finishing with this product:

Textiles such as:

Wearing apparel- for example work-wear, uniforms, sportswear, slacks, shirts, underwear, sweatshirts, sweatpants, socks, oven mitts, slippers, bathrobes, gloves, hats, scarves, jackets, incontinence pad cover stock, washable incontinence briefs and panties.

Household products, for example, upholstery, curtains, wall coverings, mops, dishcloths, yarns, cords, toweling and blankets, sheets, pillowcases.

Synthetic fiber wipes, tissues, sponges (non-food contact).

Automotive, boat, train and airplane seats and seat coverings.

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DRY FILM PRESERVATION:

THIS PRODUCT PROTECTS THE APPLIED DRY FILM ITSELF AND DOES NOT PROTECT THE UNDERLYING SURFACE FROM ATTACK BY ALGAE, FUNGI, MILDEW OR BACTERIA.

For the Dry Film Preservation of Flooring and Other Non-Food Contact Adhesives, Caulks, Sealants, Grouts and Patching Compounds:

Flooring Adhesives: For fungal control add 1500 ppm of this product and for bacterial control add 4800 ppm. (Add 1.5 lbs. of this product to 1000 lbs. of adhesive to control fungus and add 4.8 lbs. per 1000 lbs. of adhesive to control bacteria.)

Caulks/Sealants: For fungal control add 4100 ppm of this product and for bacterial control add 10000 ppm of this product. (Add 4.1 lbs. of this product per 1000 lbs. of caulk/sealant to control fungus, add 10 lbs. of this product to control bacteria.)

Grouts/Patching Compounds: For fungal control add 2000 ppm of this product and for bacterial control add 8000 ppm of this product. (Add 2 lb. of this product to 1000 lbs. of grouts/patching compounds to control fungus and 8 lbs. of this product to control bacteria.)

For the Dry Film Preservation of Aqueous Latex and Other Types of Architectural and Industrial Non-Marine Paints, Foams and Coatings Including Powder Coatings: Addition of 2000 ppm up to 10000 ppm of this product can inhibit the growth of algae, bacterial slime, mildew, and other fungi. It can be added at any time during the formulation procedure. For example, the dry film of a house paint having a density of 10 lbs. per gallon can be protected against the growth of algae, bacterial slime, mildew and other fungi by the addition of 10000 ppm of this product. (Add 2 lbs to 10 lbs. of this product to 100 gallons of wet paint.)

***For the Dry Film Preservation of Residential Latex Paints Against Fungus or Algae:**

Use a minimum of 5000 ppm of this product. For maximum protection against the growth of fungus or algae, use 10,000 ppm of this product. For control of bacterial growth on the dry paint film surface, use 5000 ppm of this product. (Add a minimum of 5 lbs. of this product to 100 gallons of wet paint, with a density of 10 lbs per gallon, to control fungus or algae. Add a maximum of 10.0 lbs. of this product to 100 gallons.)

***For the Dry Film Preservation of Joint Compounds, Glazing Compounds and Wood**

Fillers: Addition of 2000 ppm up to 10000 ppm (2 lbs to 10.0 lbs. of this product per 1000 lbs. of formulation) of this product will inhibit microbial growth (bacteria and fungi) in the dry film of these products. This product can be added at any time during the formulation procedure.

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***For the Control of Mildew and Bacteria In Styrene Butadiene and Natural Rubber, Thermoplastic Resins, and Textiles Used In the Manufacture of the Following Non-Food/Non-Medical Products:** Rubber bands, Carpet Fibers; Carpet Backings; Rubber or Rubber Backed Bath Mats; Foam Underlay For Carpets; Synthetic, Non-Leather Materials; Foam Stuffing for Cushions and Mattresses; Wire and Cable Insulation; Vinyl, Linoleum and Synthetic Floor Coverings; Wall Coverings; Plastic Furniture; Athletic Flooring and Mats; Mattress Liners, Covers or Ticking; Molding; Mats; Gaskets; Weather Stripping; Coated Fabrics For Furniture Cushions, Boat Covers, Sails, Tents; Tarpaulins; Awnings; Non-Surgical Rubber Gloves; Garbage Bags, Refuse Containers; Bathtub Appliques; Garden Hose; Non-Potable Water Pipe; Ductwork for industrial, hospital, residential, and commercial heating and cooling; Shower Curtains; Sponge or Fiber Mops; Household Use Sponges; Toilet Brush Receptacles, Toothbrush Receptacles (Non Bristle Contact); Non-Medical Scrub Brushes; Sink Mats and Drain Boards; Storage Containers; Soap Dish Holders; Towel Bars and Components of Footwear.

Addition of 2000 ppm up to 8000 ppm (2 lbs to 8 lbs./1000 lbs. of formulation) of this product can inhibit the growth of mildew & bacteria in styrene butadiene rubber & thermoplastic resins such as vinyl chloride-vinyl acetate copolymers, polyurethanes, polyamides, polyolefins, polystyrene, polyesters and acrylonitrile copolymers. It can be added at a time during the formulation procedure that will insure uniform distribution throughout the polymer system. Add by pouring or by use of metering equipment. For example, to inhibit mildew growth in polyurethane footwear components, add 4000 ppm (4 lbs./1000 lbs. of formulation) of this product to the polyurethane formulation.

***For the In Can Preservation of Latex Emulsions, Clay, Mineral, Pigment and Guar Gum Slurries Used In the Manufacture of Adhesives, Caulks, Patching Compounds, Sealants and Grouts:** A dosage of 2000 ppm up to 10,000 ppm is recommended to control bacteria and fungi. This dosage is equivalent to 2 lbs to 10 lbs. of this product per 1000 lbs. of slurry. It may be added at any time during the formulation procedure.

***To Inhibit the Growth of Bacteria and Fungi In Dry Wall and Gypsum, Pearlite, Plaster-Like, Mineral Based, or Cellulose Derived Building Materials Used In the Manufacture of Ceilings, Ceiling Tile, Walls and Partitions:** Addition of 2000 ppm up to 8000 ppm of this product (2 lbs to 8 lbs. of product per 1000 lbs. of the formulation, i.e., wet slurry) will inhibit the growth of bacteria and fungi. It can be added at any time during the formulation procedure. Alternatively the product may be added to latex or other types of coating systems routinely applied to the surfaces of walls, ceiling tiles, partitions, etc. at the same dosage as above.

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***INDIRECT FOOD CONTACT USES:**

To Control Growth of Bacteria and Fungi In Adhesives Used For Food Packaging: For food packaging adhesives, at use temperatures up to 120°F, and subject to Good Manufacturing Practices, including the conditions specified in 21 CFR 175.105 (a) and (b), add a dosage of 1500 ppm to a maximum of 2000 ppm of this product (1.5 to 2.0 lb. of this product per 1000 lbs. of food packaging adhesive) at a point where thorough mixing will take place.

To Control Growth of Bacteria and Fungi In Latex Emulsions or Aqueous Inorganic Slurries Used in the Manufacture of Food-Contact Coated Paper: To control the growth of bacteria and fungi in aqueous paper coatings and paper coatings components including latex, starch solutions, and mineral or pigment slurries (clay, kaolin clay, calcium carbonate, or titanium dioxide) at a dosage not to exceed 1000 ppm of this product in the paper coatings components and not to exceed 200 ppm of this product in the paper coating formulation. Add this product at any point in the paper coating process.

*Not for use in California.

ZINC OMADINE® PRODUCT LICENSING & PATENT NOTICE

This product contains ZINC OMADINE® and may be used in the preparation of paints with zinc oxide in accordance with the label and processes, compositions and methods claimed in U.S. Patents 6,096,122; 5,939,203; 5,883,154; 5,562,995; and 5,518,774; European Patents 0963291; 0857087; and 0807152; and their other corresponding foreign patents. Purchase of this product from Lonza, Inc. gives the purchaser a nonexclusive license to use this product in the processes, compositions and methods claimed in the above-mentioned patents, and the royalty for this license is incorporated into the purchase price of the product.

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