



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 21, 2021

Leesha Square
Regulatory Assistance
Lonza Inc.
412 Mt. Kemble Avenue Suite 200S
Morristown, NJ 07960

Subject: Label Amendment – Adding Master Batch Use in Plastics
Product Name: Zinc Omadine Powder - Lonza Industrial Microbiostat
EPA Registration Number: 6836-390
Received Date: 8/6/2019
Action Case Number: 00221639

Dear Leesha Square:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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.

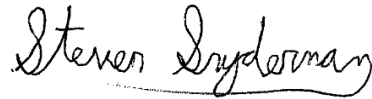
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6) you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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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 Terria Northern via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted label

ZINC OMADINE® POWDER - LONZA INDUSTRIAL MICROBIOSTAT

ALTERNATE BRAND NAMES:

MICROKILL™ POWDER – LONZA INDUSTRIAL MICROBIOSTAT
ZINC OMADINE® POWDER - LONZA ANTIMICROBIAL
ZINC OMADINE® POWDER - LONZA FUNGICIDE
ZINC OMADINE® POWDER - LONZA

Active Ingredient:

Zinc, 2-pyridinethiol-1-oxide* 95.0%

Other Ingredients:..... 5.0%

Total: 100.0%

*Zinc Pyrithione

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 front panel with multiple columns, these components will appear in the center column or in an immediately adjacent column of the front panel: Product Brand Name, Ingredient Statement, Signal Word, Child Hazard Warning, First Aid Statement, Company Name and Address, EPA Registration Number]

Net Weight [Enter Net Weight].

MANUFACTURED FOR/BY:

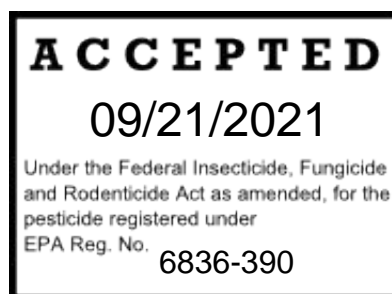
Lonza, LLC
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960

{Made in [Enter country of origin].}

EPA Reg. No. 6836-390

EPA Est. No. [Enter EPA Establishment Number]

Omadine® is a registered trademark of Arch Chemicals, Inc.



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

Zinc Omadine® Powder - Lonza Industrial Microbiostat

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Do not breathe dust. 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 after handling with soap and water, and before eating, drinking or using tobacco. Remove and wash 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 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, 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 CALL 1-800-654-6911

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.

CHEMICAL HAZARDS

Handling conditions may form dust clouds which are susceptible to ignition by electrical (static) discharge. Ground container and personnel before transferring material. 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.

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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. 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 50 lbs] 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 less than or equal to 50 lbs] 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 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 Non-Rigid Containers] Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available, or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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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, LLC. 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.

¹TEXTILES:

This product will control the growth odor causing microorganisms on textiles made of synthetic fibers such as polyester and blends. Apply this product in the following applications such that the finished product contains 0.07 to 0.36% 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.

DRY FILM PRESERVATION:

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

For the Dry Film Preservation of Flooring Adhesives, Caulks, Sealants, Grouts and Patching Compounds:

Flooring and Other Non-Food Contact Adhesives: For fungal control add 750 ppm of this product and for bacterial control add 2400 ppm. (Add 0.75 lbs. of this product to 1000 lbs. of adhesive to control fungus and add 2.4 lbs. per 1000 lbs. of adhesive to control bacteria.)

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Caulks/Sealants: For fungal control add 2083 ppm of this product and for bacterial control add 5000 ppm of this product. (Add 2.083 lbs. of this product per 1000 lbs. of caulk/sealant to control fungus, add 5.0 lbs. of this product to control bacteria.)

Grouts/Patching Compounds: For fungal control add 1000 ppm of this product and for bacterial control add 4000 ppm of this product. (Add 1 lb. of this product to 1000 lbs. of grouts/patching compounds to control fungus and 4 lbs. of this product to control bacteria.)

¹For the Dry Film Preservation of Architectural and Industrial Non-Marine Paints, Foams and Coatings, including Powder coatings: Addition of up to 5000 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 5000 ppm of this product. (Add 5 lbs. of this product to 100 gallons of wet paint.)

¹For the Dry Film Preservation of Residential Paints Against Fungus or Algae: Use a minimum of 2500 ppm of this product. For maximum protection against the growth of fungus or algae, use 5000 ppm of this product. For control of bacterial growth on the dry paint film surface, use 2500 ppm of this product. (Add a minimum of 2.5 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 5.0 lbs. of this product to 100 gallons.)

¹For the Dry Film Preservation of Joint Compounds, Glazing Compounds and Wood Fillers: Addition of up to 5000 ppm (5.0 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.

¹Not approved for use in California

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INTERMEDIATE CONCENTRATES:

This product can also be used as an antimicrobial additive in intermediate concentrations up to 25% by weight (250 lbs. of [this product] per 1000 lbs. (i.e., as a master batch) in substrates intended for further processing in an industrial environment into the finished products and formulations listed below consistent with the permitted finished product concentration. This rate applies only to intermediate manufacturing/industrial uses.

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, air filters, air filtration components and air filtration media for industrial, hospital, residential, and commercial heating and cooling; conveyor belts; 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, Components of Footwear, Toilet Seats, Hair Brushes and Hair Brush Bristles.

Addition of up to 4000 ppm (4 lbs./1000 lbs. of formulation) of this product can inhibit the growth of mildew & bacteria in styrene butadiene rubber, natural rubber, synthetic rubbers and elastomers, EPDM, textiles & 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 system. Add by pouring or by use of metering equipment. For example, to inhibit mildew growth in polyurethane footwear components, add 2000 ppm (2 lbs./1000 lbs. of formulation) of this product to the polyurethane formulation.

¹For 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 up to 5000 ppm is recommended to control bacteria and fungi. This dosage is equivalent to 5 lbs. of this product per 1000 lbs. of slurry. It may be added at any time during the formulation procedure.

¹To 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 up to 4000 ppm of this product (4 lbs. of product per 1000 lbs. of the formulation, i.e., wet slurry) will inhibit the growth of bacterial 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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¹INDIRECT FOOD CONTACT USES:

¹To 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 750 ppm to a maximum of 1000 ppm of this product (0.75 to 1.0 lb. of this product per 1000 lbs. of food packaging adhesive) at a point where thorough mixing will take place.

¹To Control Growth of Bacteria and Fungi In Latex Emulsions or Aqueous Inorganic Slurries Used For 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 500 ppm of this product in the paper coatings components and not to exceed 100 ppm of this product in the paper coating formulation. Add this product at any point in the paper coating process.

¹To Control the Growth of Bacteria/Fungi on Food Contact Surfaces Made from Polymers:

For incorporation into articles made from, or coated with FDA approved polymers. Applications include food processing equipment, conveyor belts, utensils, and storage containers. Add 750 ppm to a maximum of 1000 ppm of product (0.75 to 1.0 lb. of this product per 1000 lbs. of polymer) at a point where thorough mixing will take place. Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System." Restricted to use applications at or below room temperature. Any incorporation of this product into any food contact substance (including but not limited to non-polymer substances) other than an approved and listed food contact polymer is prohibited.

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, LLC 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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