

1258-840

8/31/2012

1/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Arch Chemical, Inc.  
5660 New Northside Drive NW  
Suite 1100  
Atlanta, GA 30328

AUG 31 2012

Attention: Nadiyah A. McCarroll  
Senior Regulatory Services Associate

Subject: Zinc Omadine ® Powder Industrial Microbiostat  
EPA Registration No. 1258-840  
Your Notification Dated August 2, 2012

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification:

- Label Modifications

General Comments:

Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)

**EPA**

United States

Environmental Protection Agency

Washington, DC 20460

☐ Registration☐ Amendment☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number <b>1258-840</b>	2. EPA Product Manager <b>Marshall Swindell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Zinc Omadine Powder Industrial Microbiostat</b>	PM# <b>33</b>	
5. Name and Address of Applicant (Include ZIP Code) Arch Chemicals, Inc. 5660 New Northside Drive, Suite 1100 Atlanta, GA 30328  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No. Product Name	

## Section - II

☐ Amendment - Explain below.☐ Resubmission in response to Agency letter dated \_\_\_\_\_☒ Notification - Explain below.☐ Final printed labels in response to Agency letter dated \_\_\_\_\_☐ "Me Too" Application☐ Other - Explain below**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

## Notification Per PR Notice 98-10

## PLEASE READ COVER LETTER FOR DETAILS.

This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: *N. McCarroll*Date: *August 2, 2012*

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No  <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt.	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify):	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name <b>Nadiyah A. McCarroll</b>	Title <b>Sr. Regulatory Services Associate</b>	Telephone No. (Include Area Code) <b>201.316.9213</b>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature <i>N. McCarroll</i>	3. Title <b>Sr. Regulatory Services Associate</b>	
4. Typed Name <b>Nadiyah A. McCarroll</b>	5. Date <b>August 02, 2012</b>	

Via FedEx

Marshall Swindell, PM-33  
Document Processing Desk [NOTIF]  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2227 S. Crystal Drive  
Arlington, VA 22202

Lonza Inc  
90 Boroline Road  
Allendale, NJ 07401, USA

Nadiyah A. McCarroll  
Regulatory Services

Tel 201-316-9213  
nadiyah.mccarroll@lonza.com

August 3, 2012

**SUBJECT: Label Notification as per PR Notice 98-10**

**PRODUCTS: Zinc Omadine® Powder Industrial Microbiostat EPA Reg. No. 1258-840**

Dear Mr. Swindell:

On behalf of Arch Chemicals Inc. (now a part of Lonza Inc.), I am submitting an application for pesticide notification to request the following changes on the above referenced product label:

- Add "Foams" in the "For the Dry Film Preservation of Architectural and Industrial Non-Marine Paints....." Paragraph of the "Directions for Use" section.
- And to include minor formatting changes.

To support this notification, the following documents are enclosed for your review:

1. Application for Pesticide Notification for each product; FRM 8750-1; which includes a signed statement certifying compliance with PR Notice 98-10.
2. One (1) copy of the proposed label with highlighted changes; and;
3. One (1) clean copy;
4. Certification with Respect to Label Integrity; and;
5. 1 CD with proposed labels

If you have any questions or need any additional information, please feel free to contact me at [nadiyah.mccarroll@lonza.com](mailto:nadiyah.mccarroll@lonza.com) or 201.316.9213.

Best Regards

Lonza Inc.

  
Nadiyah A. McCarroll  
Sr. Regulatory Services Associate

**ZINC OMADINE® POWDER INDUSTRIAL MICROBIOSTAT**

Active Ingredient:  
Zinc, 2-pyridinethiol-I-oxide\* .....95.0%  
Other Ingredients:..... 5.0%  
Total: 100.0%  
\*Zinc Pyrithione

**Keep Out of Reach of Children**  
**DANGER**

See [SIDE] [BACK] [RIGHT] [LEFT] PANEL FOR FIRST AID PRECAUTIONS

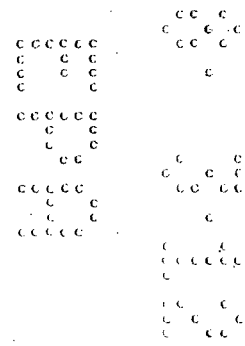
Net Wt [Enter Net Weight].

MANUFACTURED FOR/BY:  
Arch Chemicals, Inc.  
5660 New Northside Drive, Suite 1100  
Atlanta, GA 30328

{Made in [Enter country of origin].}

EPA Reg. No. 1258-840  
EPA Est. No. [Enter EPA Establishment Number]

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



**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 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 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 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.

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

Zinc Omadine Powder Industrial Microbiostat

EPA Reg. No. 1258-840

EPA Draft Label 2012-07-09

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

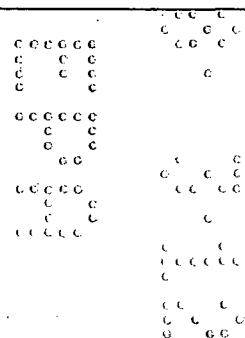
**PESTICIDE STORAGE:** Keep container tightly closed when not in use. Do not store above 130°F. Do not store with strong oxidizing agents or strong (concentrated) acids.

**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 or equal to 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 remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 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.



**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 Arch Chemicals 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.

**TEXTILES:**

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.)

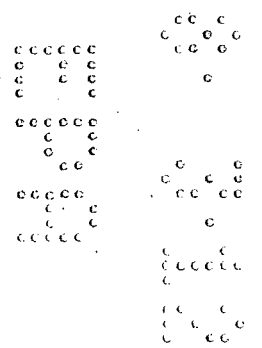
**Caulks/Sealants:** For fungal control add 2083 ppm of this product and for bacterial control add 5000 ppm of this product. (Add 2.083 lbs. of this product per 1000 lbs. of caulk/sealant to control fungus, add 5.0 lbs. of this product to control bacteria.)

**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.)

**For 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.)

**For 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.)

**For 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.





**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 and Toilet Seats.

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, 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.

**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 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.

**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 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.

## **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 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.

### **To 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 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 food packaging paper coatings.

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

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. 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.

## **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 Arch Chemicals, 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.