



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C. 20460

AUG 3 1 2012

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Lonza, Inc 90 Boroline Road Allendale, NJ 07401

Attention Nadiyah A McCarroll Sr Regulatory Services Associate

Subject Zinc Omadine 48% Dispersion Industrial Microbiostat

EPA Reg No 1258-841

Notification Letter Dated August 2, 2012

This letter acknowledges receipt of the Notification identified above submitted under the provisions of section 3(c)(9) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 This Notification requests

- Add "Foams" in the "For Dry Film Preservation of Architectural and Industrial Non-Marine Paints "Paragraph for the "Directions for Use" Section
- Minor Formatting changes
 - 1 Manufactured FOR/BY
 - 2 Made in

However, in the Note to Physician section, please add an "and" between "In case of emergency" and "for additional information call"

Based on a review of the submitted information, this notification is acceptable. This information has been made a part of your file

Should you have any questions concerning this letter, please contact Elizabeth Hernandez at (703) 347-0241

Sincerely,

Product Manager (33)

Regulatory Management Branch 1 Antimicrobials Division (7510C)

riease read instructions on reverse before co	omple form Form Apple	VCG CIVID IVO 207	O OOOO Apploy	11105 03 31 96	
	√d States		Registrài	ion	OPP Identifier Number
EPA Environ	mental Protection Age	ıcy	☐ Amendm	ent	1
Washington DC 20460					
Application for Pesticide - Section 1					
• •			Product Manager		3 Proposed Classification
1258-841		Marshall Swindell			
4 Company/Product (Name)		PM#		None Restricted	
Zinc Omadine 48% Dispersion In		33			
5 Name and Address of Applicant (Include	e ZIP Code)	6 Expedited Review In accordance with FIFRA Section 3(c)(3)(b)(I) my product is similar or identical in composition and labeling to			
Arch Chemicals or identical in composition and labeling to 5660 New Northside Drive Suite 1100					
	EPA Reg No				
Atlanta GA 30328	Product Name				
Check if this is a new address					
Section – II					
Amendment Explain below Final printed labels in response to Agency letter dated					
Resubmission in response to Agency letter dated Me Too Application					
Notification Explain below Other Explain below					
Explanation Use additional page(s) if necessary (For Section I and Section II)					
•					
Notification as 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					
mider sections 12 and 14 of the first					
Signature ///// Call Date 1/8-1/2 20/2					
Section – III					
1 Material This Product Will Be Packaged In					
Child Resistant Packaging	Unit Packaging	T w	ater Soluble Packa	ging	2 Type of Container
Yes*	Yes		Yes		Metal
l ∏ No	□ No		No No		Plastic
*Certification must be	70.77	No per If	Yes	No per	= 1
submitted		- 1	ckage wgt	container	Glass
Submineu		1		j	Paper
2 1	4.0() Det 1	Contour		5 7 01	Other (Specify)
3 Location of Net Contents Information	` '	Container		5 Location of L	LAUGI DIFECTIONS
Label Contain	CI			On Label	
VIII 1 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Does does do			Un labeling	g accompanying product
6 Manner in Which Label is Affixed to	Product Lithog Paper		Other		
	Stencil	•			
Section – IV					
1 Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application)					
Nama		*			
Name	Title	**	7 A		Telephone No (Include Area Code)
Nadiyah A McCarroll	Title	**	Services Associ	ate	Telephone No ('ncl ade Area Code) 201 316 9213
	Title S	r Regulatory S	Services Associ	ate	201 316 9213
Nadıyah A McCarroll	Title S Certification	r Regulatory S	·····		
Nadıyah A McCarroll I certify that the statements I have made	Certification on this form and all attachment	r Regulatory S	ccurate and comple	ete I acknowledge	6 Date Application Received
Nadıyah A McCarroll I certify that the statements I have made that any knowingly false or misleading s	Certification on this form and all attachment	r Regulatory S	ccurate and comple	ete I acknowledge	201 316 9213
Nadıyah A McCarroll I certify that the statements I have made	Certification on this form and all attachment tatement may be punishable by	r Regulatory S	ccurate and comple	ete I acknowledge oplicable law	6 Date Application Received
I certify that the statements I have made that any knowingly false or misleading s	Certification on this form and all attachment tatement may be punishable by	r Regulatory S s thereto are true as fine or imprisonme itte r Regulatory S	ccurate and comple ont or both under ap	ete I acknowledge oplicable law	6 Date Application Received

Lonza

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 nadıyah mccarroll@lonza com

August 2 2012

SUBJECT Label Notification as per PR Notice 98-10

PRODUCTS Zinc Omadine [®] 48% Dispersion Industrial Microbiostat EPA Reg. No. 1258-841

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 the at nadiyah mccarroll@lonza.com or 201 316 9213

Best Regards

Lonza Inc

Nadivah A. McCarroll

Sr Regulatory Services Associate

Zinc Omadine 48% Dispersion Industrial Microbiostat

ACTIVE INGREDIENT

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

KEEP OUT OF REACH OF CHILDREN **DANGER**



SEE [SIDE] [BACK] [RIGHT] [LEFT] PANEL FOR FIRST AID AND PRECAUTIONS

Net Weight [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 1258-841 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 Harmful if swallowed or absorbed through skin. Do not get in eyes on skin, or on clothing. 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 after handling with soap and water, and before eating, drinking or using tobacco Remove 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 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 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

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. 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 > 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 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.

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 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

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 up to 10000 ppm of this product can inhibit the growth of algae bacterial slime mildew and other fungilit 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 fungility by the addition of 10000 ppm of this product. (Add 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 up to 10000 ppm (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

1910

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 up to 8000 ppm (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 up to 10,000 ppm is recommended to control bacteria and fungi This dosage is equivalent 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 up to 8000 ppm of this product (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

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

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

Note Text in [Square Brackets] are notes to the label reviewer Text in {Curly Brackets} is optional Zinc Omadine 48% Dispersion Industrial Microbiostat EPA Reg No 1258-841 Page 7 of 7

EPA Draft label 2012-08 02