

1258-1328

8/23/2012

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

AUG 23 2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Attention: Leigh Ann Richardson
Regulatory Supervisor

Subject: AW03 Granular
EPA Reg. No. 1258-1328
Notification Letter Dated July 23, 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:

- Relocation of First Aid and Precautionary Statements to page 2
- Addition of optional statement 'Peligro', Spanish translation of 'Danger'
- Addition of the statement "Read all precautionary statements and first aid statements before use" to the front panel
- Relocation of the company name, address, EPA registration number, and EPA establishment number to the first page
- Deletion of NPIC emergency contact information
- Dosage tables combined into one chart
- Reference to dosage table in 'Maintenance-Monthly' section
- Reduction in maintenance dosage rate in dosage table

In addition, the following changes were noticed and are acceptable:

- "Inert ingredients" replaced with "other ingredients"
- Removal of sentence "FOR DISPOSAL OF A CONTAMINATED OR DECOMPOSING PRODUCT SEE EMERGENCY HANGLING" from storage & disposal directions

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,

A handwritten signature in black ink that reads "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1

Antimicrobials Division (7510C)

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EPA Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 1258-1328	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AW03	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Arch Chemicals, Inc. – Arch is now owned by Lonza 5660 New Northside Dr, NW, 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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Not Subject to PRIA

Label Notification to request to move First Aid from the front panel, delete the emergency information paragraph, revise the directions for use, and other minor changes. Refer to 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: Leigh Ann Richardson Date: 7/23/2012

Section – III

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

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Leigh Ann Richardson	Title Regulatory Supervisor	Telephone No. (Include Area Code) 678-627-2126
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 <u>Leigh Ann Richardson</u>	3. Title Regulatory Supervisor	
4. Typed Name Leigh Ann Richardson	5. Date <u>7/23/2012</u>	

Via Fed Ex

Mr. Marshall Swindell, PM -33
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Arch Chemicals, Inc.
5660 New Northside Drive
Suite 1100
Atlanta, GA 30328
USA

Leigh Ann Richardson
Lonza Microbial Control
Regulatory Services

Tel: 678-627-2126
Fax: 678-627-2081
LeighAnn.Richardson@Lonza.com

July 23, 2012

**SUBJECT: AW03 Granular, EPA Reg. No. 1258-1328
Application for Label Notification**

Dear Mr. Swindell:

I am submitting an application to make the following changes to the above named product label:

1. First Aid and Precautionary Statements have been moved to page 2, and add a Note to reviewer and the following referral statement have been added to page 1: "See [left] [right] [back] [side] panel for Precautionary and First Aid Statements." The reason we are asking for this allowance is due to the size of some of our packaging. The smaller sizes present a challenge to fit all of the required language on the front panel. Our note to reviewer includes the statement, "If the First Aid Statements are placed on the front panel of the final graphic label, the statement below will not be used." The intent of that statement is that when space is not an issue, the First Aid language would appear on the front panel and the referral statement would not be used.
2. Add the Spanish translation to DANGER (PELIGRO) as optional for the front panel.
3. Add the statement "Read all precautionary statements and first aid statements before use" to the front panel.
4. Move the company name, address, and EPA numbers to the first page.
5. Delete the following paragraph that was located below the First Aid section: "For emergency information on this product you may also call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center: 1-800-222-1222." This information is not on any of our other registrations and is not required on consumer pesticidal products. Please note that we already have our own emergency phone number on the label (IN CASE OF EMERGENCY CALL: 1-800-654-6911).
6. Minor revisions to the use directions to provide better consumer clarity. The changes are highlighted on page 5 of the enclosed proposed label.
 - a. Combined the two separate dosage tables into one chart.
 - b. Under Maintenance – Monthly section: Made a reference to the dosage table.


c. In the Dosage Table: reduce the Maintenance dosage rate. A reduction is requested based on consumer testing.

Please find enclosed the following documents in support of this notification:

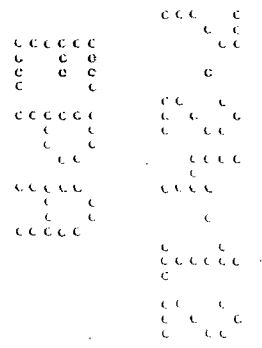
- Application for Pesticide (8570-1)
- Certification with Respect to Label Integrity
- 1 copy of the proposed label with changes highlighted
- 1 CD with proposed label

If you have any questions or need any additional information, please feel free to contact me at 678-627-2126.

Sincerely,
Arch Chemicals, Inc.



Leigh Ann Richardson
Regulatory Supervisor



Note to reviewer:

[All text in brackets [AAA] is optional and may/may not be included on final printed label]

{All text in braces {AAA} is for information purposes and will not appear on final printed label}

AW03 Granular

ACTIVE INGREDIENT: Zinc Sulfate Monohydrate 98.0%

OTHER INGREDIENTS: 2.0%

TOTAL: 100.0%

Contains 35.5 % elemental zinc

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

Read all precautionary statements and first aid statements before use.

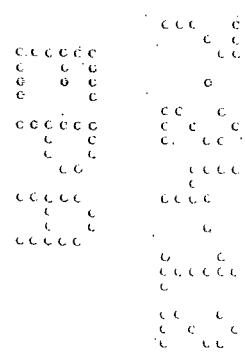
{Note to reviewer: Although this product has a "Danger" signal word, as per the EPA label review manual "The Agency may permit reasonable variations in the placement of the First Aid statement as long as the reference statement, "See First Aid (or Statement of Practical Treatment) on (identify appropriate panel)" appears on the front panel." If the First Aid Statements are placed on the front panel of the final graphic label, the statement below will not be used :}

See [left] [right] [back] [side] panel for Precautionary and First Aid Statements

Manufactured for:

Arch Chemicals, Inc.
P.O. Box 724438
Atlanta, GA 31139-1438

EPA Reg. No.: 1258-1328
EPA Est. No.: XXX-yy-zz
Net Wt. ###



✓ **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 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 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

✓ **IN CASE OF EMERGENCY CALL: 1-800-654-6911**

PRECAUTIONARY STATEMENTS:

✓ **HAZARDS TO HUMANS AND DOMESTIC ANIMALS:**

Corrosive. Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing dust or spray mist. Wear protective goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

✓ **PHYSICAL AND CHEMICAL HAZARDS:**

Avoid contact with strong oxidizers.

✓ {Environmental hazards statement for end-use products in containers less than 50 pounds (solid) use only the first sentence. All others use the full paragraph.}

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. 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 Systems (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 & DISPOSAL:** {Optional statements – usage depends on whether or not refillable or nonrefillable containers are used and whether or not product is packaged for household/residential use only}

↓ {Nonrefillable container - household/residential use}

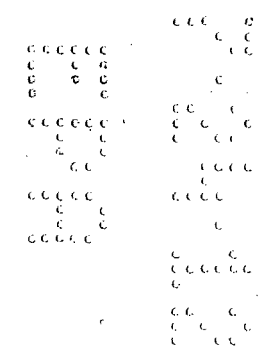
[Keep this product dry in its tightly closed container when not in use. Store in a cool, dry, well-ventilated area. Keep away from heat or open flame. Nonrefillable container. Do not reuse or refill this container. Rinse empty container thoroughly with water to dissolve all material prior to disposal. Offer for recycling if available. Do not contaminate food or feed by storage or disposal or cleaning of equipment.]

✓ {Refillable container – household/residential use}

[Keep this product dry in its tightly closed container when not in use. Store in a cool, dry, well-ventilated area. Keep away from heat or open flame. Do not contaminate food or feed by storage or disposal or cleaning of equipment. Refillable container. Refill this container with zinc sulfate monohydrate only. Do not use this container for any other purpose. Rinse empty container thoroughly with water to dissolve all material prior to disposal.]

✓ {Nonrefillable container - non-household/residential use}
[Keep this product dry in its tightly closed container when not in use. Store in a cool, dry, well-ventilated area. Keep away from heat or open flame. Do not contaminate food or feed by storage or disposal or cleaning of equipment. Nonrefillable container. Do not reuse this container. Offer for recycling if available. Rinse empty container thoroughly with water to dissolve all material prior to disposal.]

✓ {Refillable container - non-household/residential use}
[Keep this product dry in its tightly closed container when not in use. Store in a cool, dry, well-ventilated area. Keep away from heat or open flame. Do not contaminate food or feed by storage or disposal or cleaning of equipment. Refillable container. Refill this container with zinc sulfate monohydrate only. Do not use this container for any other purpose. Cleaning of this container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. Rinse empty container thoroughly with water to dissolve all material prior to disposal.]



Swimming Pool Use

✓ **[WHY YOU SHOULD USE THIS PRODUCT:**

This product will prevent the growth of algae for complete pool enjoyment. [[Product name or This product] is a key component of the [brand] System.] It is convenient and easy to use. For best results, use with other [brand] pool care products. [For crystal clear pool water follow our [brand] System]. [Consult your authorized [brand] dealer for advice on the system that best suits your pool and your lifestyle.]
[Take a pool water sample to your authorized [brand] dealer regularly for a detailed water analysis.]]

✓ **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

✓ **[How to apply:]**

[Add product either directly to pool or through the skimmer while pump is in operation according to the dosage table below.]

[Pool Opening]

[AW03 Granular brand]

✓ **[Start-Up]**

To prevent visible algae from growing in your pool:

1. Add Start-up Dosage (see table below) of [AW03 Granular Brand] to establish level needed to begin protecting your pool.
2. Continue with [BRAND] sanitizer system treatment.

✓ **[Maintenance - Monthly]**

1. Monthly add [this product] [AW03 Granular brand] per the dosage table, or take water sample to your [BRAND] Authorized Dealer to test for [AW03 Granular brand] level.
2. If [AW03 Granular brand] is less than 0.5 ppm add a Start-Up dose; if level is greater or equal to 0.5 ppm add a Maintenance dose according to the table below.]

✓ **[Pool Closing]**

1. Add a Closing dose of [AW03 Granular brand] according to the table below.
2. Follow recommended [brand] pool closing procedure.]

Dosage Table			
Pool Size, Gallons (round to nearest 5,000 gallons)	Start-Up Dosage Number of Ounces	Maintenance Dosage Number of Ounces	Closing Dosage Number of Ounces
5,000	3	1	2
10,000	6	2	4
15,000	9	3	6
20,000	12	4	8
25,000	15	5	10
30,000	18	6	12
35,000	21	7	14
40,000	24	8	16

