

1258-1342

8/22/2012

1/11

AUG 22 2012

Leigh Ann Richardson
Regulatory Supervisor
Arch Chemicals, Inc -Arch is now owned by Lonza
5660 New Northside Drive, NW, Suite 1100
Atlanta, GA 30328

Subject AW35-36
EPA Registration No 1258-1342
Notification Date July 23, 2012
EPA Receipt Date July 24, 2012

Dear Ms Richardson,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c)9 and PR Notice 98-10

Proposed Notification

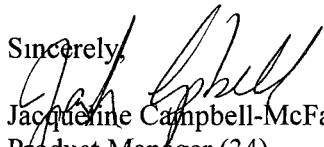
- Label revisions moving First Aid from the front panel to page 2
- Adding a Note to reviewer page 1
- Adding the Spanish translation to DANGER (PELIGRO) optional to the front panel
- Adding marketing claims page 7

General Comments

Based on a review of the submitted materials, your notification to revise your label and add marketing claims is acceptable A copy of this letter has been made a part of the record on file for future reference

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at rivas.lorena@epa.gov When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing

Sincerely,



Jacqueline Campbell-McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES									
SYMBOL	7510P								
SURNAME	J. Rivas								
DATE	8/29/12								

<p>EPA Environmental Protection Agency Washington DC 20460</p>	<p>States <input type="checkbox"/> Registrant <input type="checkbox"/> Amendment <input type="checkbox"/> Other <input checked="" type="checkbox"/></p>	<p>OPP Identifier Number</p>
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Application for Pesticide - Section 1

<p>1 Company/Product Number 1258-1342</p>	<p>2 EPA Product Manager Monesha Harris</p>	<p>3 Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted</p>
<p>4 Company/Product (Name) AW35-36</p>	<p>PM# 32</p>	
<p>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</p> <p><input type="checkbox"/> Check if this is a new address</p>		<p>6 Expedited Review In accordance with FIFRA Section 3(c)(3)(b)(I) my product is similar or identical in composition and labeling to</p> <p>EPA Reg No Product Name</p>

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 for the addition of marketing claims and request to move First Aid from the front panel 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

<p>1 Material This Product Will Be Packaged In</p>			
<p>Child Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No *Certification must be submitted</p>	<p>Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes Unit Packaging wgt No per container</p>	<p>Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes Package wgt No per container</p>	<p>2 Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)</p>
<p>3 Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container</p>	<p>4 Size(s) Retail Container VARIOUS</p>	<p>5 Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product</p>	
<p>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</p>			

Section – IV

<p>1 Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application)</p>		
<p>Name Leigh Ann Richardson</p>	<p>Title Regulatory Supervisor</p>	<p>Telephone No (Include Area Code) 578-67-2126</p>
<p>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</p>		<p>6 Date Application Received (Stamped)</p>
<p>2 Signature <u>Leigh Ann Richardson</u></p>	<p>3 Title Regulatory Supervisor</p>	
<p>4 Typed Name Leigh Ann Richardson</p>	<p>5 Date <u>7/23/2012</u></p>	

3/11



Via Fed Ex

Ms Monisha Harris PM 32
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
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Atlanta GA 30328
USA

Leigh Ann Richardson
Lonza Microbial Control
Regulatory Services

Tel 678 627 2126
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LeighAnn.Richardson@Lonza.com

July 23 2012

SUBJECT AW35 36, EPA Reg No 1258 1342
Application for Label Notification

Dear Ms Harris

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 included 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 was that when space was not an issue the language First Aid statements 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 We would also like to add the following optional marketing statements which are highlighted on page 7 of the enclosed proposed label

[Test and Add*]{Application frequency per routine maintenance directions }
[*Please refer to directions for use]

[[Brand or POOLIFE] 3-Step System]
{The [Brand or POOLIFE] 3-Step System below may be placed on the label to allow easy product identification by consumers }
[[Brand or POOLIFE] 3-Step System
Step 1 [Sanitize It!] [POOLIFE [AW35-36 Additional Brand Name]]
Step 2 [Shock It!] [POOLIFE Exclusive Pool Care Collection TurboShock Shock Treatment]
Step 3 [Defend It!] [POOLIFE Exclusive Pool Care Collection Defend +]]

{Optional marketing statements that may be used with pool sanitization with 3 inch tablets }
[Controlled Release Sanitizer for use in Automatic Feeders or Floaters]
[Slow Dissolving Sanitizer for use in Automatic Feeders or Floaters]
[Multifunctional] {or} [Multi-action][3][Chlorinating][Tablets]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER Corrosive Causes irreversible eye damage Causes eye and skin burns May be fatal if inhaled or absorbed through skin Harmful if swallowed Irritating to nose and throat

- Open in a well-ventilated area Avoid breathing dust and fumes
- Do not get in eyes on skin or on clothing Wear goggles and rubber gloves For additional protection of skin, wear long sleeves and long pants
- Wash hands after handling and before eating drinking chewing gum using tobacco or using the toilet
- Remove 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 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

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

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

PHYSICAL AND CHEMICAL HAZARDS

DANGER If product is exposed to small amounts of water, it can react violently to produce heat and toxic gas and spatter Do not add water to this product Add only into water

- [Do not mix this product with a small amount of water Only add this product directly to your pool]
{This statement will appear on Pool use labels only }
- Do not allow to become wet or damp before use

Can react with other materials, including other water treatment products, to cause fire, explosion, and the release of toxic gases

- Keep all foreign matter including other water treatment products away from this product
- Use only clean and dry utensils to dispense this product
- Do not allow this product to contact other water treatment products If used in a skimmer make sure skimmer is completely clean and free of residue from other water treatment products before putting this product in a skimmer
- Avoid spilling this product

Exposure to heat can cause this product to rapidly decompose, leading to fire, explosion, and the release of toxic gases

- Store in a cool dry well-ventilated area away from heat or open flame

Strong oxidizing agent This product can increase fire intensity

- Keep away from heat and from flame and burning material (like a lighted cigarette)

Contamination or improper use may cause fire, explosion or the release of toxic gases Do not allow product to contact any foreign matter, including other water treatment products If product is exposed to small amounts of water, it can react violently to produce heat and toxic gases and spatter Do not add water to this product Add only into water {Optional – for use on residential use swimming pool products} **[Do not remove floater or other dispensing device from water for an extended period of time if it contains a tablet or tablet residue]** {The following optional statement is for use on residential use swimming pool and spa products } **[Do not mix this product with a small amount of water Only add directly to your pool]** **Corrosive Causes irreversible eye damage and skin burns Harmful if swallowed, inhaled, or absorbed through the skin**

{First sentence of paragraph below for containers 50 lb or less complete paragraph for all other sizes}

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms 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

{Household/residential use products}

STORAGE AND DISPOSAL

Pesticide Storage

{Nonrefillable containers}

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

Pesticide Disposal

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 If not discard in trash **FOR DISPOSAL OF A CONTAMINATED OR DECOMPOSING PRODUCT SEE EMERGENCY HANDLING**

EMERGENCY HANDLING In case of contamination or decomposition – Do not reseal container Immediately remove container to an open and well-ventilated outdoor area by itself Flood with large amounts of water Dispose of the container and any remaining contaminated material in an approved landfill area

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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

[AW35-36 or other brand] [tablet[s]*]¹ are a unique and effective pool water sanitizer] [Routine sanitization is important to keep your pool water free of bacteria and contaminants] [These convenient and easy to use [BRAND] [chlorinating] [tablet[s)*] are formulated to protect against chlorine loss in direct sunlight and can be used in skimmers [and] floaters [and feeders] [In addition to sanitizing [brand] [tablets] prevent algae growth and clarify your pool water] [They are designed to dissolve slowly to provide a steady source of available chlorine]

[For crystal clear pool water follow our 4 step pool care program Step 1 Test and balance pool water Step 2 Sanitize Step 3 Shock at least once a week and Step 4 Add algacide as directed by that product]

METHOD OF APPLICATION Use in a floating dispenser automatic chlorinator or feeder designed for this product or place in skimmer Use in a new chlorinating device or any device which has previously contained only this product or trichloro-s-triazinetriene If placed in the skimmer run the pump a minimum of eight hours daily **DO NOT** Use in floaters or feeders that have been used with other water treatment products **DO NOT** Throw tablets directly into pool **DO NOT** permit tablets to contact plastic pool linings or metal objects **DO NOT** Use in any chlorinating device which has been used with other chlorinating compounds

WATER BALANCE

[To provide optimum product performance swimmer comfort and crystal clear water always maintain pH from 7.2 to 7.6 total alkalinity from 80 to 120 parts per million (ppm) and calcium hardness above 200 ppm Test frequently using an HTH test kit that measures all these ranges Make any necessary adjustments promptly with the appropriate HTH pool care products Re-entry into treated pools is prohibited with chlorine levels above 4 ppm for risk of bodily injury]

{or}

[Adjust and maintain pool water pH from 7.2 to 7.6 total alkalinity from 80 to 120 parts per million (ppm) and calcium hardness above 200 ppm Test frequently using a[n] [brand] [test kit] [or] [test strips] that measure[s] all of the above ranges [Bring a pool water sample to your [brand] dealer frequently to test for water balance] Maintain free available chlorine between 1 - 4 ppm [using a stabilized chlorine product] {or} [brand granular shock]

OPENING YOUR POOL Balance pool water shock treat and stabilize your pool using [brand] Stabilizer & Conditioner and by following directions on that label Then follow "ROUTINE CHLORINATION" directions

ROUTINE CHLORINATION

{For single tablet pack}

Follow 'METHOD OF APPLICATION Add one tablet per 10 000 gallons of pool water every week or as often as needed to maintain a chlorine residual at 1-4 ppm This dosage may vary depending upon bather load water temperature and other conditions Pool must not be entered until the chlorine residual is 1-4 ppm as measured with a reliable test kit

{Directions for use with tablet form of this product in skimmer or floater}

¹ *The term tablet[s] may be replaced with stick[s] capsule[s] cube[s] cartridge[s] or other compacted form or descriptive term either singular or plural according to each respective product design

[Ensure that the skimmer basket or floater is free of any other chemicals tablets, or residue Place this product in the skimmer basket or floater Use one tablet per 10 000 gallons of water Do not add other chemicals to the skimmer or floater while this product is present Run filter pump a minimum of 8 hours per day otherwise vinyl liner damage may occur If free available chlorine goes above 4 ppm reduce skimmer flow rate or daily pump operation time Reentry into treated swimming pool is prohibited above levels of 4 ppm free available chlorine due to risk of bodily injury If chlorine residual goes below 1 ppm add enough [brand] granular shock to maintain 1-4 ppm of chlorine and increase skimmer flow rate or daily pump operation time The number of [tablets*] and frequency of use will vary with bather load water temperature rain, and pump operating time]

{Directions for use with cartridge form of this product in a [brand] feeder}
[Turn off filter pump Open [brand] feeder remove cartridge container and allow any water remaining in the empty cartridge to drain back into the feeder Dispose of empty cartridge material Refill cartridge container with new [AW35-36 or other brand] cartridge Replace cartridge container then close the feeder and turn filter pump back on Set chlorine delivery rate to maintain available chlorine at 1 – 4 ppm

After 24 hours check chlorine residual level with a test [kit [or] strip] If free available chlorine is above 4 ppm reduce the feed rate and retest in 24 hours Reentry into treated swimming pools is prohibited above levels of 4 ppm free available chlorine due to risk of bodily injury

Test chlorine residual on a regular basis and if below 1 ppm free available chlorine increase dial setting Be sure to refill cartridge when contents are fully dissolved]

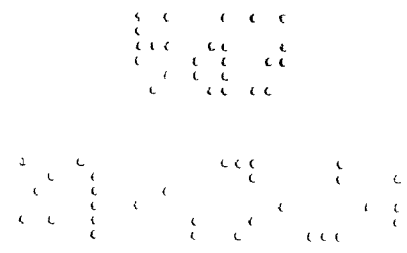


{Optional for residential use products} []

TO DETERMINE POOL CAPACITY IN U.S. GALLONS Use the appropriate formula below	
POOL SHAPE	FORMULA (Use measurement in feet)
Rectangular	Length x width x average depth x 7.5 = total gallons
Round	Diameter x diameter x average depth x 5.9 = total gallons
Oval	Maximum length x maximum width x average depth x 5.9 = total gallons
Freeform	Surface area (sq. feet) x average depth x 7.5 = total gallons

{Optional marketing claims for all products}
[Clarifies pool water]
[Precipitating agent included]
[Assists filtration]
[Multipurpose tablet]

[Produces sparkling clean swimming pool water]
 [Restores clarity to pool water]
 [Contains a clarifier {or} [filter aid]]
 [Keeps [pool] water clear]
 [Contains clarifying additive]
 [[With] {or} [Contains] built-in clarifier]
 [Keeps pool water clean and crystal clear]
 [Sparkling pool water]
 [For crystal clear sparkling blue water]
 [4-in-1 Action Sanitizes prevents algae prevents staining & scale formation and clarifies water]
 [Four products in One]
 [3-in-1 Action Sanitizes prevents algae and clarifies water]
 [Three products in One]
 [[2-in-1] {or} [Dual] Action Sanitizes and prevents algae]
 [Two products in One]
 [For routine use in automatic feeders, floaters and skimmers]
 [[Provides] 84% available chlorine]
 [Stabilized [Sanitization] {or} [Sanitizer] {or} [Chlorinator]]
 [[Stabilized] {or} [Sun resistant] {or} [Sun [protected {or} protection]] for extended chlorine life]
 [With {or} Contains built-in resistance to sunlight]
 [Sanitizes pool water]
 [Swimming pool sanitizer]
 [Sanitizer [for Chlorine Pools]]
 [Sanitizer for swimming pool water]
 [Concentrated chlorinator for routine use]
 [Multi action sanitizer]
 [[Multifunctional] {or} [Multi-action] [chlorinating] [tablet]]
 [Protects against bacteria and algae]
 [Kills [bacteria and] [controls] algae]
 [Algaecide]
 [[With] {or} [Contains] built-in algae [protection] {or} [fighter]]
 [Kills bacteria and destroys organic contaminants]
 [Kills and prevents bacteria, while maintaining proper chlorine levels]
 [[Chlorinates] {or} [Chlorine lasts] up to one week]
 [Convenient one week dosage]
 [Convenient to use]
 [Easy, economical convenient to use]
 [One tablet treats 10 000 gallons [for a week]]
 [Provides long lasting chlorination]
 [Regulates chlorine levels]
 [Totally Soluble]
 [Slow dissolving]
 [Controlled release sanitizer]
 [Individually wrapped for easy handling]
 [For all pool types]
 [Compatible with all pool surfaces]
 [Gentle on Equipment and Liners]
 [For Pop-Up Pools]
 [Step 1 Balance]
 [Step 2 Sanitize]
 [Step 3 Shock]



[Step 4 Prevent Algae]
 [Step 1 {in the [brand] System}]
 [Leaves no residue]
 [Non-staining formula]
 [Will not cause staining]
 [Softens Water] {or} [Water softener]
 [Protection pool surfaces and equipment]
 [Protects pool equipment [against scaling] for longer life]
 [Prevents metal staining [and] [[] corrosion] [and scale formation]]
 [Corrosion inhibitor]
 [With built in scale preventative & sunlight protector]
 [Sequestering agent]
 [Reduces scale formation]
 [Enhanced filter performance]
 [New improved {or} advanced formula]
 [Innovative patented exclusive technology]
 [Test and Add*]{Application frequency per routine maintenance directions }
 [*Please refer to directions for use]

[[Brand or POOLIFE] 3-Step System]
 {The [Brand or POOLIFE] 3-Step System below may be placed on the label to allow easy product identification by consumers }

[[Brand or POOLIFE] 3-Step System
 Step 1 [Sanitize It!] [POOLIFE [AW35-36 Additional Brand Name]]
 Step 2 [Shock It!] [POOLIFE Exclusive Pool Care Collection TurboShock Shock Treatment]
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{Optional marketing statements that may be used with pool sanitization with 3 inch tablets }
 [Controlled Release Sanitizer for use in Automatic Feeders or Floaters]
 [Slow Dissolving Sanitizer for use in Automatic Feeders or Floaters]
 [Multifunctional] {or} [Multi-action][3][Chlorinating][Tablets]
 [Multifunctional] {or} [Multi-action][3][Chlorinating][Tabs]
 [[[3] Chlorinating Tablets] [with patented exclusive technology]]
 [4-in-1 Action][3][Chlorinating][Tabs]
 [3" Sanitizer Tablets]

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