

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

MAY - 6 2013

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Joanna Holcombe, Senior Regulatory Services Associate Arch Chemicals, Inc. 5660 New Northside Drive NW Suite 1100 Atlanta, GA. 30328

Subject:

Vantocil P Microbiocide

EPA Registration Number 1258-1252 Notification Date: April 15, 2013 Notification Pin Punch: April 18, 2013

Dear Ms. Holcombe:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c) 9.

## **Proposed Notifications**

• Revision of Active Ingredient name to Poly(hexamethylenebiguanide) hydrochloride, change Inert Ingredients to Other Ingredients, add and First Aid to back, right, or left panel.

#### **General Comments**

Based on a review of the material submitted, the Notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075 or Luminello.Tom@EPA.GOV.

Sincerely,

Jacqueline Hardy Product Monagor o

Product Manager 34

Regulatory Management Branch II Antimicrobials Division (7510P)

Please read instructions on reverse before	comptent in x contribut	oved, OMB No. 20	770 0000, 11pp10vai	s 05-31-98		
⊕ ED A	Usd States	•	Registra	tion	OPP Ide	entifier Number
SEPA Enviro	onmental Protection Ag	encv	Amendn	nent		
	Washington, DC 20460	,	Other			
	Applicat	ion for Pestici	ide - Section 1			
1. Company/Product Number		2. EPA Product Manager		3. Proposed Classification		
1258-1252			e McFarlane			
4. Company/Product (Name)	a i d a	PM# <b>34</b>			None None	Restricted
Vantocil® P Microbiocide  5. Name and Address of Applicant (Include ZIP Code)		6. Expedited Review. In accordance with FIFRA Sec		tion 2(a)(2)(b)(I) m	ny product is similar	
Arch Chemicals, Inc.	ue ZII Coue)		omposition and lab		11011 3(6)(3)(0)(1), 11	ly product is similar
5660 New Northside D	rive NW, Suite 1100		•	· ·		
Atlanta, GA 30328		EPA Reg. No.				
		Product Name				
Check if this is a new address						
		Section -	II			
Amendment - Explain below.			Final printed lab	els in response to A	gency letter dated	· .
Resubmission in response to Age	ncy letter dated	Final printed labels in response to A  "Me Too" Application		gency retter dated_	<del></del>	
Notification - Explain below.	ney retter dated	Other - Explain below				
Explanation: Use additional p	age(s) if necessary (For S	Section Land Se		·		
Explanation, Coo additional p		t Subject to	•			
Label Notification to chang		ive ingredien letter for deta		accepted nam	ie, etc. Please	e see cover
This notification is consistent w						
changes have been made to the						
violation of 18 U.S.C. Sec. 100 consistent with the terms of PF						
subject to enforcement action a			is product may	y De III VIOIALIOI	I OI FIFTA AND	i i iiiay be
i subject to enforcement action a	and behällies under sec	tions 12 and 1				
subject to emorcement action a	and penallies under sec	tions 12 and 1		4/ 4:-		
Signature: Dama	Accombe	tions 12 and 1		4-15-2	013	_
On	Holombe	tions 12 and 1 Section – I	4 of FIFRA.  Date:	4-15-2	0(3	
On	Holombe		4 of FIFRA.  Date:	4-15-2	0(3	
Signature: Joanna	Holombe	Section – I	4 of FIFRA.  Date:	4-15-2	2. Type of Conta	
Signature: Power Will Be Pack  Child-Resistant Packaging  Yes*	aged In: Unit Packaging Yes	Section – I	4 of FIFRA.  Date:  III	4-15-2	0(3	
Signature: Joanna  1. Material This Product Will Be Pack Child-Resistant Packaging	aged In: Unit Packaging Yes No	Section – I	4 of FIFRA.  Date:  Ultivater Soluble Packa  Yes  No	4-15-2	2. Type of Conta	
Signature: Power Will Be Pack  Child-Resistant Packaging  Yes*	aged In: Unit Packaging Yes No If "Yes"	Section – I	4 of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No ""Yes"	4-/5-2 aging No. per	2. Type of Conta	
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No	aged In: Unit Packaging Yes No If "Yes"	Section – I	4 of FIFRA.  Date:  Ultivater Soluble Packa  Yes  No	4-15-2	2. Type of Conta	
Signature: Power Will Be Pack  Child-Resistant Packaging  Yes*  No  *Certification must be	aged In: Unit Packaging Yes No If "Yes"	Section – I	4 of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No ""Yes"	4-/5-2 aging No. per	2. Type of Conta  Metal Plastic Glass	iner
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Information	aged In: Unit Packaging Yes No If "Yes" Unit Packaging wgt.	Section – I	4 of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No ""Yes"	No. per container  5. Location of	2. Type of Conta  Metal Plastic Glass Paper	iner
Signature:  1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted	aged In:  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt.	Section – I	4 of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No ""Yes"	H-/5-2	2. Type of Conta  Metal Plastic Glass Paper Other (Speci	iner
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Information	aged In: Unit Packaging Yes No If "Yes" Unit Packaging wgt.	Section – I	4 of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No ""Yes"	No. per container  5. Location of	2. Type of Conta  Metal Plastic Glass Paper Other (Speci	inerfy)
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Information	aged In:  Unit Packaging Yes No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail Narious O Product \( \times \) Lithog	Section – I	4 of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No ""Yes"	No. per container  5. Location of	2. Type of Conta  Metal Plastic Glass Paper Other (Speci	fy)
Signature:   1. Material This Product Will Be Pack Child-Resistant Packaging  Yes*  No *Certification must be submitted  3. Location of Net Contents Information Label  Contain	aged In:  Unit Packaging Yes  No If "Yes" Unit Packaging wgt.  on 4. Size(s) Retail various o Product  Lithog Paper	Section – I	4 of FIFRA.  Date:  UII  Vater Soluble Packa  Yes  No  "Yes" ackage wgt.	No. per container  5. Location of	2. Type of Conta  Metal Plastic Glass Paper Other (Speci	fy)
Signature:   1. Material This Product Will Be Pack Child-Resistant Packaging  Yes*  No *Certification must be submitted  3. Location of Net Contents Information Label  Contain	aged In:  Unit Packaging Yes No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail Narious O Product \( \times \) Lithog	Section – I	A of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No  "Yes" ackage wgt.	No. per container  5. Location of	2. Type of Conta  Metal Plastic Glass Paper Other (Speci	fy)
Signature: Pour Signature: 1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Information Label Contain Con	aged In:  Unit Packaging Yes  No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail Various  O Product Paper Stenci	Section – I  No. per If container  Container  graph glued led  Section – I	4 of FIFRA.  Date:  III  Vater Soluble Packa  Yes  No  "Yes" ackage wgt.  Other  U	No. per container  5. Location of On Label On labelin	2. Type of Conta  Metal Plastic Glass Paper Other (Speci	fy)
Signature:   1. Material This Product Will Be Pack Child-Resistant Packaging  Yes*  No *Certification must be submitted  3. Location of Net Contents Information Label  Contain	aged In:  Unit Packaging Yes  No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail Various  O Product Paper Stenci	Section – I  No. per If container  Container  graph glued led  Section – I	4 of FIFRA.  Date:  III  Vater Soluble Packa  Yes  No  "Yes" ackage wgt.  Other  U	No. per container  5. Location of On Labelin On labelin	2. Type of Conta  Metal Plastic Glass Paper Other (Speci Label Directions	fy) roduct
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Informatio Label Contain 6. Manner in Which Label is Affixed to	aged In:  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail  various  o Product  Paper  Stenci	Section – I  No. per If container  Container  graph glued led  Section – I  dividual to be container	A of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No  "Yes" ackage wgt.  Other  V  acted, if necessary,	No. per container  5. Location of On Labelin On labelin	2. Type of Conta  Metal Plastic Glass Paper Other (Speci Label Directions  ag accompanying processing accompanying accompanying accompanying accompanying accompanying accompanying accompanying accompanying accompanying acc	fy) roduct
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Information Label Contain 6. Manner in Which Label is Affixed to	aged In:  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail  various  o Product  Paper  Stenci	Section – I  No. per If container  Container  graph glued led  Section – I  dividual to be contained	A of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No  "Yes" ackage wgt.  Other  V  acted, if necessary,	No. per container  5. Location of On Labelin On labelin corrections this applicate	2. Type of Conta    Metal   Plastic   Glass   Paper   Other (Specilabel Directions)   Contact	fy) roduct
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Informatio Label Contain 6. Manner in Which Label is Affixed to	aged In:  Unit Packaging Yes No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail ner  Various  O Product  A Paper Stenci	Section — I  No. per If container  Container  graph glued led  Section — I  dividual to be container  Sr. Regulatory	A of FIFRA.  Date:  Use of FIFRA.  Date:  Vater Soluble Packa  Yes  No  "Yes" ackage wgt.  Other  V  acted, if necessary,	No. per container  5. Location of On Labelin On labelin	2. Type of Conta    Metal   Plastic   Glass   Paper     Other (Speci Label Directions   Contact   Contact	fy) roduct
Signature: Pour Signature: 1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Information Label Contain Contain Contain Contain Contain Contain Contain Contain Contain Complete items direct Name  Joanna Holcombe	aged In:  Unit Packaging Yes No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail ner  Various  O Product  A Lithog Paper Stenci  Illy below for identification of inter  Certification	Section — I  No. per If container  Container  Graph glued led  Section — I  dividual to be container  Sr. Regulatory	Date: Date:  Uvater Soluble Packa Yes No "Yes" ackage wgt.  Other  V acted, if necessary,	No. per container  5. Location of On Labelin On labelin sociate	2. Type of Conta    Metal   Plastic   Glass   Paper     Other (Speci Label Directions   Contact   Contact	fy) roduct c nclude Area Code) c ication Received
1. Material This Product Will Be Pack Child-Resistant Packaging Yes* No *Certification must be submitted  3. Location of Net Contents Informatio Label Contain 6. Manner in Which Label is Affixed to	aged In:  Unit Packaging Yes No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail ner  Various  O Product  A Lithog Paper Stenci  Certification of inter  Certification on this form and all attachmen	Section — I  No. per If container  Container  Container  Section — I  dividual to be container  Correction — I  container	Date: Date:  Uvater Soluble Packa Yes No "Yes" ackage wgt.  Other  V acted, if necessary, or Services Asia	No. per container  5. Location of On Labelin On labelin sociate	2. Type of Conta    Metal   Plastic   Glass   Paper     Other (Speci Label Directions   Contact   Contact	fy) roduct c nclude Area Code) c ication Received
Signature:	aged In:  Unit Packaging Yes No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail Norious  O Product  A Size(s) Retail Various  O Product  Lithog Paper Stenci  tly below for identification of in  Title S  Certification e on this form and all attachmen statement may be punishable by	Section — I  No. per If container  Container  Graph glued led  Section — I dividual to be container  Sr. Regulatory  In the street of the stre	Date: Date:  III  Vater Soluble Packa Yes No "Yes" ackage wgt.  Other  Vacted, if necessary, A Services Assaccurate and complement or both under a	No. per container  5. Location of On Labelin On labelin  to process this applicable law.	2. Type of Conta    Metal   Plastic   Glass   Paper     Other (Speci Label Directions   Contact   Contact	fy)  roduct  c  c  clude Area Code)  g  ication Received  amped)
Signature:   1. Material This Product Will Be Pack Child-Resistant Packaging  Yes*  No *Certification must be submitted  3. Location of Net Contents Information Label Contain  6. Manner in Which Label is Affixed to the contents Information  1. Contact Point (Complete items direct Name Joanna Holcombe  I certify that the statements I have made that any knowingly false or misleading 2. Signature	aged In:  Unit Packaging Yes  No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail No If "Yes" Unit Packaging wgt.  On 5. Size(s) Retail Iner Various O Product  A Size(s) Retail Paper Stenci  Certification of ine Title S  Certification e on this form and all attachmen statement may be punishable by  3. T	Section — I  No. per If container  Container  Graph glued led  Section — I dividual to be container  Br. Regulatory  In the street of the stre	Date: Date:  III  Vater Soluble Packa Yes No "Yes" ackage wgt.  Other  Vacted, if necessary, A Services Assaccurate and complement or both under a	No. per container  5. Location of On Labelin On labelin  to process this applicable law.	2. Type of Conta    Metal   Plastic   Glass   Paper     Other (Speci Label Directions   Contact   Contact	fy)  roduct  c  c  clude Area Code)  g  ication Received  amped)
Signature:	aged In:  Unit Packaging Yes  No If "Yes" Unit Packaging wgt.  On 4. Size(s) Retail No If "Yes" Unit Packaging wgt.  On 5. Size(s) Retail Iner Various O Product  A Size(s) Retail Paper Stenci  Certification of ine Title S  Certification e on this form and all attachmen statement may be punishable by  3. T	Section — I  No. per If container  Container	Date: Date:  III  Vater Soluble Packa Yes No "Yes" ackage wgt.  Other  Vacted, if necessary, A Services Assaccurate and complement or both under a	No. per container  5. Location of On Labelin On labelin  to process this applicable law.	2. Type of Conta    Metal   Plastic   Glass   Paper     Other (Speci Label Directions   Contact   Contact	fy)  roduct  c  c  clude Area Code)  g  ication Received  amped)

Via FedEx

Ms. Jacqueline McFarlane, PM-34 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 Arch Chemicals, Inc. 5660 New Northside Drive NW, Suite 1100 Atlanta, GA 30328, USA

Joanna Holcombe Lonza Microbial Control Regulatory Services

Tel 678-627-2336 Fax 678-627-2081 joanna.holcombe@lonza.com

April 15, 2013

SUBJECT: Vantocil® P Microbiocide, EPA Reg. No. 1258-1252

**Application for Label Notification** 

Dear Ms. McFarlane:

Lonza is submitting an application to make alterations to page one of the abovementioned product label. The name of Vantocil® P Microbiocide's active ingredient has been changed to the ANSI accepted name of Poly(hexamethylenebiguanide) hydrochloride. "Inert Ingredients" has been changed to "Other Ingredients," and the referral statement for optional placement of Precautionary Statements now includes First Aid and additional panel location options. Please find the enclosed documents in support of this notification:

- · Application for Notification;
- Certification with Respect to Label Integrity;
- · CD with label; and
- One copy of the proposed label with changes highlighted.

If you have any questions or need any additional information, please feel free to contact me at 678-627-2336.

Sincerely, Lonza Inc.

Joanna Holcombe

Sr. Regulatory Services Associate

Note to reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label] {Items in braces {AAA} are for information purposes and will not appear on final label}

# Vantocil® P Microbiocide

For Formulation Of Disinfectants And Algicides

### KEEP OUT OF REACH OF CHILDREN

# WARNING

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

EPA Reg. No. 1258-1252 EPA Est. No. (as indicated on container)

Net Contents: (insert container size here)

Country of origin (insert country)]
[Manufactured in (insert country)]
[DOT symbols]
[BARCODE]
[Vantocil® is a registered trademark of Arch UK Biocides LTD.]

[See Precautionary Statements and First Aid on [Side] [Back] [Right] [Left] Panel]



#### PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

**WARNING:** Causes substantial but temporary eye injury. Harmful if swallowed. Do not get concentrate in eyes or clothing. Avoid contact with skin. Avoid breathing vapor or mist. Wear goggles or face shield when handling concentrate. Wash thoroughly with soap and water after handling. Wash clothing and decontaminate footwear before reuse. May cause allergic skin reaction.

#### **ENVIRONMENTAL HAZARDS**

This product 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. Do not contaminate water by cleaning of equipment or disposal of wastes.

#### 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**: 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 Swallowed:** Call a Poison Control Center or doctor immediately for treatment advice. Do not induce vomiting. Avoid alcohol.

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 Additional Information In Case Of Emergency Call Toll Free 1-800-654-6911



#### **DIRECTIONS FOR USE:**

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

Technical material for repackaging or reformulating disinfectants, sanitizers, fungicides and algicides. Vantocil P is for the manufacture of: swimming pool sanitizers and disinfectants for use in commercial, industrial, and residential settings. Vantocil P may be used to formulate sanitizers and disinfectants for use in food handling/storage establishments, premises and equipment, including food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. Repackers or reformulators must obtain their own registrations with EPA.

#### STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE**: Open dumping is prohibited. Keep container closed when not in use. Store in a dry, well-ventilated area away from heat and open flames

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

{one of the following statements}

{for containers ≤5 gallons}

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose of in a sanitary landfill.

{for containers >5 gallons}

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill the container ¼ full with water. 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. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose of in a sanitary landfill.