

72674-5

5/30/2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 30 2002

Rosemary Long
Registration/Business Specialist
AVECIA, Inc.
1405 Foulk Road
Wilmington, DE 19850-5457

Subject: Notification per PR Notice 98-10
Vantocil® IB Microbiocide
EPA Registration No. 72674-5
Application Dated: May 6, 2002

Dear Ms. Rosemary Long:

This letter acknowledges receipt of your notification, submitted in connection with registration under FIFRA 3(c)9 and PR Notice 9-10.

Proposed Notification

- Add advisory statement "VANTOCIL IB is registered with the Environmental Protection Agency and has been granted EPA Registration No. 72674-5"

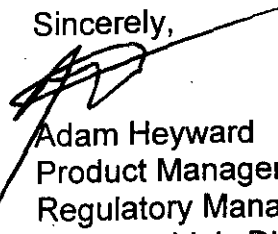
General Comments

Based on a review of submitted material, the following comment applies:

The application for notification is acceptable and has been made a part of the records for this file.

Should you have any questions regarding this letter, please contact me at 703-308-6422.

Sincerely,


Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

CONCURRENCES

SYMBOL	SURNAME	DATE



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72674-5	2. EPA Product Manager ADAM HEYWARD	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) VANTOCIL IB MICROBIOCIDE	PM # 34	
5. Name and Address of Applicant (Include ZIP Code) AVECIA INC. 1405 FOULK ROAD WILMINGTON, DE 19850-5457 <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.)

TO ADD ADVISORY STATEMENT "VANTOCIL IB IS REGISTERED WITH THE ENVIRONMENTAL PROTECTION AGENCY AND HAS BEEN GRANTED EPA REGISTRATION NO. 72674-5" TO THE TECHNICAL INFORMATION BULLETIN PORTION OF THE LABEL.

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	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
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 Label 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 Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name ROSEMARY LONG	Title REGISTRATION/BUSINESS SPECIALIST	Telephone No. (Include Area Code) 302-477-8133
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 	3. Title REGISTRATION/BUSINESS SPECIALIST	
5. Typed Name ROSEMARY LONG	5. Date MAY 6, 2002	

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Avecia

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Avecia Biocides

1405 Foulk Road, P.O. Box 15457
Wilmington, Delaware 19850-5457

Telephone: (302) 477-8000
Fax: (302) 477-8120

CERTIFIED MAIL -- RETURN RECEIPT

May 6, 2002

Mr. Adam Heyward, Product Manager 34
Antimicrobials Division
C/O Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Subject: **VANTOCIL® IB Microbiocide**
EPA Reg. No. 72674-5
■ Notification to Add Advisory Statement to Label

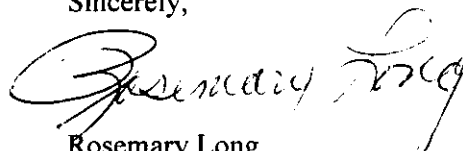
Dear Mr. Heyward:

Avecia Inc. wishes to notify EPA of the addition of an advisory statement "*VANTOCIL IB is registered with the Environmental Protection Agency and has been granted EPA Registration No. 72674-5*" to the Technical Information Bulletin portion of the subject product label.

Enclosed is a completed notification form, a PR Notice 98-10 Certification Statement, and a copy of the draft label with the additional statement highlighted in yellow for your convenience.

We look forward to being advised that this notification is acceptable. Please contact me at the above address or at (302) 477-8133 if there are any questions.

Sincerely,



Rosemary Long,
Registration/Business Specialist

Enclosures



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PR Notice 98-10 Certification Statement

PRODUCT: **VANTOCIL IB Microbiocide**

EPA Reg. No: 72674-5

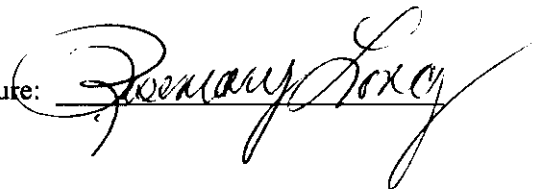
REGISTRANT: Avecia Inc.

NOTIFICATION TO: Add Advisory Statement to Vantocil IB Microbiocide Label

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.

Company Agent: Rosemary Long
Title: Registration/Business Specialist
Date: May 6, 2002

Signature: _____



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Vantocil® IB

Microbiocide

NOTIFICATION
Data Reviewed: 5/2/02
Reviewed By: APR

Technical Information Bulletin

General Information

VANTOCIL® IB is a highly effective preservative for use in a wide variety of applications including oil-in-water and water-in-oil emulsions, industrial reagents, silicone systems, cellulose solutions and oil recovery systems. VANTOCIL IB can also be used for the preservation of animal hides and skins and certain textile and cellulosic products.

VANTOCIL IB is registered with the Environmental Protection Agency and has been granted EPA Registration No. 72674-5.

Physical Properties

Specific Gravity	
at 68°F:	1.04 (approx.)
Density at	
68°F, lb/gal:	8.8 (approx.)
Flash Point,	
°F(TCC):	>200
Pour Point, VF:	32
SH at 77°F:	5.5 (approx.)

Chemical Description

VANTOCIL IB is an aqueous solution of polyhexamethylene biguanide hydrochloride and is soluble in water and stable under all normal conditions of storage. The active ingredient, itself, is heat stable and nonvolatile.

Compatibility

VANTOCIL IB is a mild cationic compound and is compatible with nonionic and cationic compounds. VANTOCIL IB, nonionics and cationics should be metered through separate pumps. VANTOCIL IB is not compatible with oxidizing chemicals, most anionic compounds and copper. VANTOCIL IB is precipitated by strong alkalies and complex phosphates. When doubt exists as to the compatibility of VANTOCIL IB with other compounds, bottle tests at the concentrations to be used should be made with the material in question.

Directions for Use

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

Product

Silicones:

Use VANTOCIL IB at levels of 100-5,000 ppm for the preservation of silicone systems such as silicone emulsions and silicone dispersions.

Dosage

1 lb. to 50 lb.
VANTOCIL IB
per 10,000 lb.
product

Tunnel Pasteurization:

For the preservation of waters used in tunnel pasteurization and tunnel cooling of sealed packages of canned and bottled foodstuffs, use VANTOCIL IB at levels of 100-1,000 ppm.

13 fl. oz. to 1 gal.
VANTOCIL IB
per 1,000 gal.
tunnel
pasteuriza-
tion water

Aqueous Industrial Chemicals:

For the preservation of aqueous industrial chemicals such as reagents, oil-in-water emulsions, water-in-oil emulsions, textile spin finish lubricants, wash water and cellulose solutions, use VANTOCIL IB at levels of 100-5,000 ppm.

1 lb. to 50 lb.
VANTOCIL IB
per 10,000 lb.
product

Leather Processing:

Use VANTOCIL IB at levels of 100-3,000 ppm for the preservation of leather processing solutions.

1 lb. to 30 lb.
VANTOCIL IB
per 10,000 lb.
product



Product**Dosage*****Aqueous Based Polymer Latices:***

Use VANTOCIL IB at levels of 500-5,000 ppm for the preservation of aqueous based polymer latices such as polyvinyl acetate and polyvinyl alcohol. Do not use to preserve latices used for paper coating compositions that may contact food.

5 lb. to 50 lb.
VANTOCIL IB
per 10,000 lb.
product

Aqueous Mineral Slurries:

Use VANTOCIL IB at levels of 500-5,000 ppm for the preservation of aqueous mineral slurries such as calcium carbonate, titanium dioxide. Do not use to preserve slurries used for paper coating compositions that may contact food.

5 lb. to 50 lb.
VANTOCIL IB
per 10,000 lb.
product

Aqueous Based Adhesives:

Use VANTOCIL IB for the preservation of aqueous based adhesives such as animal glues, latex adhesives based on polyvinyl acetate, PVA, etc., starch, synthetic, dextrin, casein and other glues at a concentration of 500-5,000 ppm. May be used in aqueous based latex adhesives intended for food packaging applications at a maximum use level of 5,000 ppm.

5 lb. to 50 lb.
VANTOCIL IB
per 10,000 lb.
product

Industrial Electrocoats:

Use VANTOCIL IB at levels of 1,000 - 5,000 ppm for the preservation of electrocoat resins and deposition systems.

10 lb. to 50 lb.
VANTOCIL IB
per 10,000 lb.
product

Household Consumer Products:

Use VANTOCIL IB at levels of 250 - 2,500 ppm for the preservation of liquid and solid or paste consumer products such as surface cleaners, floor cleaners, fabric stain removers, fabric softeners, fabric conditioners, laundry detergents, laundry additives, automotive care silicone emulsions, and automotive cleaning products.

2.5 lb. to 25 lb.
VANTOCIL IB
per 10,000 lb.
product

Product**Dosage*****Preservation of Fresh Animal Hides and Skins:***

To preserve the integrity of fresh animal hides and skins prior to or during processing, use 15 fluid ounces to 3 gallons. Add the appropriate quantity of VANTOCIL IB to the brine solution during the curing operation or treat hides or skins with an appropriately diluted aqueous solution during other portions of the processing operation. The specific use rate and contact time needed to control microbial attack will depend upon the degree of decomposition of the hides or skins prior to treatment.

1.0-2.6 lbs. of
VANTOCIL IB
per 1,000
pounds of
hides or
skins

Cellulosic Materials and Textiles

VANTOCIL IB can be used as an agent to control the growth and action of microorganisms, and control generation of odors, on textiles such as cotton, cotton blends, cellulosic materials, and synthetic fibers such as non-wovens, tissues, paper and pulps.

VANTOCIL IB is diluted and applied to give 0.025-2.0% on the dry weight of the substrate. Application is by conventional means such as padding, spraying, soaking or exhaustion. The optimum conditions for application of the dilute solution are pH 6.5-8 and temperature of 20-30°C.

The following are examples of products (substrates) suitable for antimicrobial finishing with VANTOCIL IB:

Textiles such as: household products, for example, upholstery, carpet, curtains, wall coverings, mops, dishcloths, yarns, cords, and towelling.

Cellulosics such as: wipes, tissues, sponges, paper products (non-food contact) such as filters and cellulose pulp.

Oil Recovery

Not for use in oil recovery systems which employ holding ponds for spent liquids. Do not apply in, over or near marine and/or estuarine oil fields.

Specific rates for use of VANTOCIL IB should be determined by bacteriological tests made prior to treatment. These tests should establish (a) the presence of microorganisms, (b) the severity of the problem, and (c) required treating ratio. The effectiveness of a treatment can be evaluated by similar bacteriological tests. The compatibility of VANTOCIL IB with the water should be determined prior to treatment.

Some suggested treatment methods and treating rates for water systems include:

Oil Field Injection Waters

1. SLUG METHOD - When the system is noticeably fouled, apply 4 gallons of VANTOCIL IB per 1,000 barrels of water (95 ppm of product). VANTOCIL IB should be added to the system at a point where it will be uniformly mixed. Repeat on a weekly basis, or as needed to establish control.

When microbial control is evident, the treating rate may be lowered to 2 gallons of VANTOCIL IB per 1,000 barrels of water (47 ppm of product) weekly, or as needed to maintain control.

Badly fouled systems should be cleaned before treatment is begun.

2. CONTINUOUS METHOD - Before beginning a continuous treatment, apply a slug treatment of 4 gallons of VANTOCIL IB per 1,000 barrels of water (95 ppm of product). Continue treatment by applying 0.15 to 0.8 gallons (19 to 102 ounces) of VANTOCIL IB per 1,000 barrels of water (4 to 20 ppm of product).

Drilling Muds

1. Calculate the total volume of the drilling mud system, and using this volume calculate the number of gallons of VANTOCIL IB needed to produce a concentration of approximately 3,000 ppm. For example 126 gallons of VANTOCIL IB per each 1,000 barrels of total volume will produce this concentration.

2. While the system is circulating, add the amount of VANTOCIL IB calculated above in a thin stream.

3. As the well depth increases, increasing the total volume of the system, add additional VANTOCIL IB as required to maintain the proper concentration.

Workover Fluids

1. Calculate the total volume of the workover fluid system, and using this volume calculate the number of gallons of VANTOCIL IB needed to produce a concentration of approximately 3,000 ppm. For example, 126 gallons of VANTOCIL IB per each 1,000 barrels of total volume will produce this concentration.
2. Add VANTOCIL IB into the system.
3. Circulate the workover fluid system until the fluid returns clear.
4. Shut the system down and idle for several hours.
5. Remove the workover fluid. The well should be ready for productive use.

General

VANTOCIL IB is an effective preservative in most aqueous compositions. The concentration required to give protection depends on factors such as the susceptibility of the system to microbiological degradation, the extent to which microorganisms can gain access and the type of microorganisms present.

Packaging

VANTOCIL IB is packaged in 55-gallon drums and 5-gallon pails.

WARNING

Keep Out of Reach of Children

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get concentrate in eyes or on 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.

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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 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.

Medical Emergency Information Center 1-800-286-7850

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.

Environmental Hazards

This pesticide is toxic to fish. Do not discharge into lakes, streams, ponds, 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

Prohibitions

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

Pesticide Disposal

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

Container Disposal

Triple rinse (or equivalent). 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 information on spills, call 1-800-424-2466

Safe Handling Information

Refer to the Material Safety Data Sheet (MSDS) available from Avecia Biocides for information on the safe use, handling and disposal of this product.

For technical information, literature, sample and order information, please contact Customer Services: 800-523-7391.

For more information, visit our website at www.aveciabiocides.com.

VANTOCIL is a registered trademark of Avecia Inc.

FOR YOUR PROTECTION

AVECIA Inc. ("AVECIA") warrants that this product conforms to the chemical description on the label and that it is reasonably fit for the purposes stated on the label when used in accordance with AVECIA's directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions reasonably foreseeable to AVECIA, and the buyer or user assumes the risk of any such use. AVECIA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WAR-

RANTY OF MERCHANTABILITY. (Statements herein, therefore, should not be construed as representations or warranties.)

IN NO EVENT SHALL AVECIA BE LIABLE FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, ON ANY THEORY WHATSOEVER, INCLUDING NEGLIGENCE, AND AVECIA's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price. Statements concerning the use of products or the formulations

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ISO 9002
FS 22484

Avecia Biocides

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Wilmington, DE 19850