72674-5 2/19/2003 Page 139

February 19, 2003

Mark E. Burt Regulatory Manager Avecia, Inc. 1504 Foulk Road Wilmington, DE 19850-5457

Subject:

Vantocil IB

EPA Registration No. 72674-5 Application Date; January 17, 2003 EPA Received Date: January 23, 2003

Dear Mr. Burt:

This acknowledges receipt of our notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

Addition of blankets as a use site

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your files for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6233.

Adam Heyward
Product Manager 34
Regulatory Management Branch II

CONCURRENCE Antimicrobials Division (7510 C)

SURNAME DATE

Q-10-03

Sincerely,

229

The read instructions of	a myerre hefere comule	dina form		Earn Ann	roved	OMB No. 1	070.008	O. Approval expires 2-28-	
United States Environmental Protection Washington, DC 20460				Agency		Registra Amenda Other	tion	OPP Identifier Number	
		Application	on for Pestici	de - Sect	ion				
1. Company/Product Number 72674-5			2. EPA Product Meneger ADAM HEYWARD				3. Proposed Classification		
4. Company/Product (Name) VANTOCIL IB			PM#	PM# 34					
5. Name and Address of A AVECIA INC., 1504 WILMINGTON, DE	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No								
Check if ti	his is a new address		Produ	ict Name _					
			Section -						
Resubmission in re Notification - Expla Explanation: Use additi NOTIFICATION TO ADD A 1. Material This Product V Child-Resistant Packaging Yes No	sponse to Agency letter in below. ional page(s) if necessar AN INDOOR NONFOOD S	y. (For section	_	Agency lett "Me Too" A Other - Expl	er date Applica Jain be	tion. low.	R NOTICE Container Metal Plastic		
rtification must	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container		-	Glass Paper Other (S	Specify)	
Label Container 5. Manner in Which Label is Affixed to Product Litha			etail Container 5. Location of Lab				el Directio	ons	
	·	Steric	Section - I	v					
1. Contact Point Comple	te items directly below f	for identification			if nece	ssary, to pro	cess this	application.)	
Name MARK E. BURT			Title REGULATORY MANAGER				Telephone Nn. (Include Area Code) 302-477-8129		
	tements I have made on any knowlingly false or le law.		all attachments th					6. Date Application Received (Stamped)	
2. Connature MMh	3. Title • • • REGULATORY MANAGER				••••	• • • • • • • • • • • • • • • • • • • •			

JANUARY 17, 2003

5. Date

4. Typed Name

MARK E. BURT

PR Notice 98-10 Certification Statement

Product:

VANTOCIL IB

EPA Reg. No.: 72674-5

Registrant: Avecia Inc.

Notification to: Add an Indoor Nonfood Site for an Antimicrobial Product

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:

M.E. Burt

Signature: MM-G/m/

Title: Regulatory Manager

Date: January 17, 2003



Avecia

Avecia Biocides

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

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

Certified - Return Receipt

January 17, 2003

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, NW
Washington, DC 20460

NOTIFICATION
Date Reviswed: 210 3
Reviewed By: 6704

Subject:

VANTOCIL IB

EPA Reg. No. 72674-5

- Notification: To Add an Indoor Nonfood Site, Blankets

Dear Mr. Heyward:

Avecia wishes add the indoor nonfood site, blankets, to the labeling for VANTOCIL IB. We believe that this site can be added to the product labeling by notification as provided for by PR Notice 98-10. In support of this notification, enclosed is a completed notification form, a PR Notice 98-10 Certification Statement, and five (5) copies of revised labeling, with the added site highlighted in yellow.

Thank you for your cooperation and we look forward to begin notified that the notification is acceptable.

Please contact me at the above address, or by phone at (302) 477-8129, or by e-mail at mark.burt@avecia.com, if there are any questions.

Sincerely,

Mark E. Burt, Ph.D.

Regulatory Manager

VANTOCIL® '3

MICROBIOCIDE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND
DOMESTIC ANIMALS

WARNING

CAUSES SUBSTANTIAL BUT TEMPORARY EYE IN-JURY. HARMFUL IF SWALLOWED. DO NOT GET CONCENTRATE IN EYES OR CLOTHING. AVOID CONTACT WITH SKIN. AVOID BREATHING VAPOR OR MIST. WEAR GOGGLES OR FACE SHELD WHEN HANDLING CONCENTRATE. WASH THOR-OUGHLY WITH SOAP AND WATER AFTER HANDLING. WASH CLOTHING AND DECONTAMINATE FOOTWEAR BEFORE REUSE. MAY CAUSE ALLERGIC SKIN REACTION.

ENVIRONMENTAL HAZARDS: THIS PESTICIDE IS TOXIC TO FISH. 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 SYSTEM (NPDES) PERMIT AND THE PERMITTING AUTHORITY HAS BEEN NOTHED 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: METAL CONTAINERS: TRI-PLE RINSE (OR EQUIVALENT), THEN OFFER FOR RECYCLING OR RECONDITIONING, OR PUNCTURE AND DISPOSE OF IN A SANITARY LANDFILL OR BY OTHER APPROVED STATE AND LOCAL PROCE-DURES.

> FOR INFORMATION ON SPILLS, CALL 1-800-424-2466.

WARNING

KEEP OUT OF REACH OF CHILDREN

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 IMMEDI-ATELY 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.

HOT LINE NUMBER: 1-800-286-7850.

HAVE THE PRODUCT CONTAINER OR LABEL WITH YOU WHEN CALLING A POPSION CONTROL CENTER OR DOCTOR, OR GOING FOR TREATMENT.

NOTE TO PHYSICIAN

PROBABLE MUCDSAL DAMAGE MAY CONTRAINDICATE THE USE OF GASTRIC LAVAGE.

NOTIFICATION
Date Reviewed: 2-10-03
Reviewed By: Carriage

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

VANTOCIL IB MICROBIOCIDE IS A HIGH-ACTIVITY MI-CROBIOCIDE FOR USE IN APPLICATIONS SUCH AS OIL-IN-WATER AND WATER-IN-DIL EMULSIONS, IN-DUSTRIAL REAGENTS, SILICONE SYSTEMS AND CELLULOSE SOLUTIONS. VANTOCIL IB MICROBIO-CIDE CAN ALSO BE USED FOR THE PRESERVATION OF ANIMAL HIDES AND SKINS. SEE TECHNICAL IN-FORMATION BULLETIN 64-0000-025 FOR DIRECTIONS FOR USE.

NOTICE TO BUYER AND USER: SELLER WAR-RANTS THAT THIS PRODUCT CONFORMS TO THE CHEMICAL DESCRIPTION ON THE LABEL AND IS REASONABLY FIT FOR THE PURPOSES STATED ON THE LABEL WHEN USED IN ACCORDANCE WITH DI-RECTIONS UNDER NORMAL CONDITIONS OF USE. THIS WARRANTY DOES NOT EXTEND TO THE USE OF THIS PRODUCT CONTRARY TO LABEL INSTRUC-TIONS. OR UNDER ABNORMAL USE CONDITIONS. OR UNDER CONDITIONS NOT REASONABLY FORE-SEEABLE TO SELLER, AND BUYER AND USER AS-SUME THE RISK OF ANY SUCH USE. SELLER DIS-CLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LI-OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL, OR INDIRECT
DAMAGES RESULTING FROM THE USE OR HANDUNG OF THIS PRODUCT, AND SELLER'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 THE PRODUCTS OR FORMULATIONS DESCRIBED HEREIN ARE NOT TO BE CONSTRUED AS RECOMMENDING THE INFRINGEMENT OF ANY PATENT AND NO LIABILITY FOR INFRINGEMENT ARISING OUT OF ANY SUCH USE IS ASSUMED.

EPA REG. NO.: 72674-5 EPA EST. NO.: 72674-TN-01

Avecia

Medical Emergency Information Center - 860-286-7850 Chemical Emergency Response Center - 800-424-2466 P.O. Box 15457 Wilmington Delaware 19850-5457 USA 800-435-8679

VANTOCIL is a trademark of Avecia Inc.

REV. DATE: NET CONTENTS: 07/20/01

LOT NUMBER:

PRODUCT CODE:

1

Vantocil[®] IB

Technical Information Bulletin

Microbiocide

General Information

VANTOCIL® IB is a highly effective preservative for use in a wide variety of applications including oil-inwater 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.

Physical Properties

Specific Gravity

at 68ºF:

1.04 (approx.)

Jensity at

68°F, lb/gal:

8.8 (approx.)

Flash Point,

°F(TCC): ,• Pour Point, VF: >200

rour rom, v

32

pH at 77°F:

5.5 (approx.)

Shemical 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

ANTOCIL 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 Dosage

Silicones:

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

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 pasteurization 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

MASTER

Product

Dosage

Dosage

queous 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 caronate, titanium dioxide. Do not e to preserve slurries used or 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 adheves such as animal glues, ex 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 od packaging applications at naximum 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 2.50 - 2,500 ppm for the preservation of liquid and solid or paste consumer products such as surface cleaners, floor cleaners, fabric stain removers, fabric teners, fabric conditioners, raundry detergents, laundry additives, automotive care silicone emulsions,

and automotive cleaning products.

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

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.

Product

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, toweling and blankets.

Cellulosics such as: wipes, tissues, spongés, 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

- 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 uniformily 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.
- 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

 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.

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

- 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

Oauses substantial but (emporary 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.

First Aid:

<u>in Eyes</u>: 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 ontraindicate 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 ystem (NPDES) permit and the permitting authorusy 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.

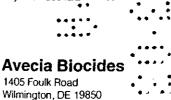
FOR YOUR PROTECTION

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 unabnormal use conditions, or under conditions reasonably foreseeable to AVECIA, and the Duyer or user assumes the risk of any such use. AVECIA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WAR-

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