72674-5 6/26/2001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 2 6 2001

Mark E. Burt, Ph.D.
Regulatory Manager **AVECIA B IOCIDES**1405 Foulk Road - P.O. Box 15457

Wilmington, Delaware 19850-5457

Attention: Dr. Mark E. Burt:

Subject:

Amended Label/Add Language for Household Consumer Products

VANTOCIL IB MICROBIOCIDE EPA Registration Number 72674-5 Your Letter Dated March 29, 2001

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you:

- 1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

	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 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 the poison control center or doctor.
	HOT LINE NUMBER
	nergency call toll free at (Registrant fill in)." container or label with you when calling a poison control center or doctor or going for treatment."
	NOTE TO PHYSICIAN
"Probable mucosal contra	aindicate the use of gastric lavage, " CONCURRENCES
1510c	
2 Collins	
6.26.01	
1320-1A (1/90)	Printed on Recycled Paper OFFICIAL

- 3. The following statements are suggested types of information that may be included in the first aid statement.
 - technical information on symptomatology;
 - use of supportive treatments to maintain life functions;
 - medicine that will counteract the specific physiological effects of the pesticide;
 - company telephone number to specific medical personnel who can provide specialized medical advice.
- 4. Submit three (3) copies of your final printed labeling before you release the product for shipment

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,

Adam Heyward

Product Manager (34)

Regulatory Management Branch II Antimicrobials Division (7510C)

Enclosure:

VANTOCIL® IS

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 SHIELD 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 EUMINATION SYSTEM (NPDES) PERMIT AND THE PERMITTING AUTHORITY HAS BEEN NOTFIED 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-

MICROBIOCIDE

WARNING

KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: IMMEDIATELY FLUSH WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES AND GET MEDICAL ATTENTION.

IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER. GET MEDICAL ATTENTION IF IRRITATION PERSISTS.

IF SWALLOWED: DRINK A LARGE QUANTITY OF WATER. DO NOT INDUCE VOMITING. AVOID ALCOHOL CALL A PHYSICIAN.

EPA REG. NO. 72874-5 EPA EST. NO. 72674-TN-01 ACCEPTED with COMMENTS in EPA Letter Dated:

JUN 26 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 72674-5

DIRECTIONS FOR USE

If is a violation of federal law to use this PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

VANTOCIL IB MICROBIOCIDE IS A HIGH-ACTIVITY MECROBIOCIDE FOR USE IN APPLICATIONS SUCH AS OIL-IN-WATER AND WATER-IN-OIL EMULSIONS, INDUSTRIAL REAGENTS, SILICONE SYSTEMS AND CELLULOSE SOLLITIONS. VANTOCIL IB MICROBIOCIDE CAN ALSO BE USED FOR THE PRESERVATION OF ANIMAL HIDES AND SKINS. SEE TECHNICAL INFORMATION 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 DIRECTIONS 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-ABLE FOR CONSEQUENTIAL, SPECIAL, OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING 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.

Avecia

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

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Vantocil[®] IB

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 68°F:

1.04 (approx.)

Density at

68°F, lb/gal:

8.8 (approx.)

Flash Point,

°F(TCC):

>200 32

Pour Point, VF: pH 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.

Technical Information Bulletin

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

ueous Based Polymer Latices:

Product

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

Dosage

Aqueous Mineral Slurries:

Use VANTOCIL IB at levels of 500-5,000 ppm for the preservation of aqueous mineral ries 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 preseron of aqueous based adhes 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.
I 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 ducts such as surface cleaners, floor cleaners, fabric stain removers, automotive care silicone emulsions, and automotive cleaning products.

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

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.

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

Dosage

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 ates 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.
- 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.

Statement of Practical Treatment

F IN EYES: Immediately flush with plenty of water for at least 15 minutes and get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF SWALLOWED: Drink a large quantity of water. Do not induce vomiting. Avoid alcohol. Call a physician.

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.

itorage 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.

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 un-

rr abnormal use conditions, or under conditions of 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-

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Avecia Biocides

1405 Foulk Road Wilmington, DE 19850

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