

64881-3

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB - 2 2007

Harvey L. Steinberg
Senior Regulatory Attorney
AEGIS Environmental Management Inc.
2205 Ridgewood Drive
Midland, MI 48642-5884

Subject: AEGIS Antimicrobial
EPA Reg. No.64881-3
Application Dated: December 27, 2006
Receipt Date: January 1, 2007

Dear Mr. Steinberg,

The following notification submitted in connection with registration under the, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c) 9 and the provisions of PR Notice 98-10 is unacceptable.

Proposed Notification

- Addition of an indoor, nonfood use site.

General Comments

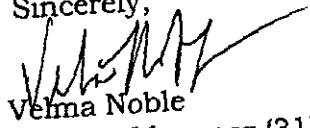
Based on a review of the material submitted, the following comments apply:
This application for notification to add an indoor, nonfood use site is unacceptable. Please resubmit to the Agency as an amendment. To add HVAC&R system components is too broad. This use requires a Risk Assessment and revised directions for use. A copy has been placed in our records for future reference.

		CONCURRENCES				
ME	M 7570C D. Kudu M 42/3/07					

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch 1
Antimicrobial Division
(7510c)0

CONCURRENCES

7510c								
D. Keller								
2/3/09								



December 27, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

**Re: Notification – Additional Indoor, Nonfood Site
AEGIS® Antimicrobial – Reg. #64881-3
AEGIS® 444-02 RTU Antimicrobial – Reg. #64881-6**

Enclosed please find completed EPA Forms 8570-1 for each of the above products. The purpose of the notification is to add an additional indoor, nonfood site for AEGIS® Antimicrobial (EPA Reg. No. 64881-3) and its ready-to-use diluted version, AEGIS® 444-02 RTU Antimicrobial (EPA Reg. No. 64881-6).

AEGIS Antimicrobial is the identical formulation as AEM 5700 Antimicrobial (Reg. No. 64881-1) and differs only in its labeling and intended use. All of our antimicrobials are registered as microbiostatic agents. AEM 5700 is already approval for use on HVAC components such as fiberglass ductboard for air handling systems as well as air filters for furnaces, air conditioners, air purification devices and recirculating air handling systems. Therefore, we believe that no additional data are required for this additional use sites for the above two products.

Enclosed with each form are their respective revised labels with the added use site highlighted for easy reference.

Sincerely,

Harvey L. Steinberg
Senior Regulatory Attorney

AEGIS ENVIRONMENTS

2205 Ridgewood Drive • Midland, MI 48642-5884
Phone: (989) 832-8180 • 1-800-241-9186 • Fax: (989) 832-7572
www.aegismicrobeshield.com

4/7

Please read instructions on reverse before completing form.

Form Approved, 4B No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 64881-3	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AEGIS Antimicrobial	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) AEGIS Environmental Management, Inc. 2205 Ridgewood Drive Midland, MI 48642-5884 <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.)

Notification of adding additional indoor, nonfood site per PR Notice 98-10.
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.

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
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt	No. per container	<input type="checkbox"/> Other (Specify) _____	
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"/>	
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 Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Harvey L. Steinberg	Title Senior Regulatory Attorney	Telephone No. (Include Area Code) (989) 832-8100
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 Senior Regulatory Attorney	
4. Typed Name Harvey L. Steinberg	5. Date December 27, 2006	

Master Label

AEGIS Antimicrobial

A SILANE QUATERNARY AMMONIUM SALT

EPA Reg. No. 64881-3

EPA Est. 34292-MI-01

ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	42%
INERT INGREDIENTS:	58%
TOTAL	100%

**CONTAINS 50% METHANOL
KEEP OUT OF REACH OF CHILDREN**

DANGER! ☠ POISON

FIRST AID

Have product container or label with you when calling Poison Control Center of doctor, or going for treatment.

- | | |
|--------------------------------|--|
| If inhaled: | <ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a Poison Control Center or doctor for treatment advice. |
| If in eyes: | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after first 5 minutes, then continue rinsing. • Call a Poison Control Center or doctor for treatment advice. |
| If in skin or clothing: | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a Poison Control Center or doctor immediately for treatment advice. |
| If swallowed: | <ul style="list-style-type: none"> • 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. |

LOT NO.

NET CONTENTS

kg.



AEGIS ENVIRONMENTAL MANAGEMENT, INC.
 2205 Ridgewood Drive, MIDLAND, MICHIGAN 48642 U.S.A.
 1-989-832-8180 © 2006 AEGIS Environmental Management, Inc.
 The AEGIS logo is a trademark of AEGIS Environmental Management, Inc.
 MADE IN U.S.A.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS.

DANGER! CORROSIVE. CONTAINS 50% METHANOL. CAUSES IRREVERSIBLE EYE DAMAGE AND SKIN IRRITATION. MAY BE FATAL IF INHALED. May be harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, rubber gloves, and protective clothing. Do not breathe vapor. . Wear a NIOSH approved respirator with any N, R, P, or HE filter. Appropriate measures should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish and aquatic invertebrates. 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 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.

Every effort should be made to contain accidental spills of concentrate to the immediate area. This may be accomplished by the use of sandbags or barrier material to confine the spill to facilitate cleanup and disposal. Contaminated sand or barrier material may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags or other absorbent materials by wiping, soaking and/or mopping and allowing the liquid to absorb onto the material. The absorbent material may then be disposed of by incineration or landfill. Floor drains in areas of material use should be protected with absorbent material or barrier material to contain accidental spills.

Inactivation of solutions containing AEGIS Antimicrobial may be accomplished by addition of an anionic surfactant, or detergent in quantity equivalent to that of AEGIS Antimicrobial in solution.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame

PRODUCT FEATURES AND BENEFITS

- AEGIS Antimicrobial imparts durable biostatic activity to the surface of a wide variety of substrates.
- AEGIS Antimicrobial is effective against mold, mildew and algae as a static agent.
- Increased efficiency – through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AEGIS Antimicrobial.
- Provides freshness and combats deterioration and discoloration caused by bacteria, fungi and algae.

DIRECTIONS FOR USE

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

FOR COMMERCIAL APPLICATIONS IN HOMES, OFFICES, AUTOMOBILES AND INSTITUTIONS AND FOR INDUSTRIAL USE ONLY. This product is registered as a microbiostatic agent for material preservation only; neither this product nor the articles treated with this product may state or imply any public health claims. Articles or substances treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) if the intended use for incorporating this material into a treated article or substance is for the protection of the article or substance itself.

APPROVED USES: AEGIS Antimicrobial is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent. AEGIS Antimicrobial can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) activity:

- Carpet, Draperies and Upholstery, Furniture, Book Covers, and Pictures
- Plastics, fiberglass, metals, glass, wood, ceramics, stone, natural materials, composites; including air filters for furnaces, air conditioners, air purification devices, automobiles, and recirculating air handling systems; automotive and vehicular parts; concrete products, roofing materials (tiles, shakes, shingles, granules, stone, membranes, felt, underlayment and synthetic overcoats); building materials and components including siding, wallboard, wood and wood composites, and insulation; HVAC&R system components; interior non-food contact hard surfaces including floors and floor covering, walls, ceilings, ceiling tiles, ceramic tile, non-food contact countertops, concrete, chrome, stainless steel, fiberglass, vinyl, porcelain, fabric and paper wall covering, wood and glass fixtures, marble, aluminum, and non-food contact cabinetry.

HOW TO USE:

MSDS INFORMATION: BEFORE HANDLING, READ PRODUCT AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET CAN BE OBTAINED BY WRITING TO AEGIS ENVIRONMENTS OR BY CALLING (989) 832-8180. A MATERIAL SAFETY DATA SHEET FOR A TYPICAL USE DILUTION AQUEOUS SOLUTION IS ALSO AVAILABLE.

Wear goggles or face shield, protective clothing, rubber gloves and respirator when handling the concentrated material. Use with proper ventilation. Undiluted AEGIS Antimicrobial contains 50 percent methanol. Avoid breathing vapors. Keep away from heat and open flame. Methanol is released during mixing, application and drying. If desired, methanol removal may be accelerated by heating dilute solution before treatment of substrate. Appropriate measures should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry.

AEGIS Antimicrobial can be applied to organic and inorganic surfaces as a dilute aqueous solution to give 0.1 to 1.0 percent by weight of active ingredients (suggested starting level is 2.5 ounces of AEGIS Antimicrobial to one gallon of water). Aqueous solutions can be prepared by simply adding the antimicrobial agent to water with stirring. NOTICE: Poor agitation when adding this silane to water can result in locally high concentrations, which may form gel particles. Surfaces can be treated with the aqueous solution by brushing, dipping, padding, soaking, spraying or fogging until adequately wet, or applying by foaming techniques. After applying treatment, the surface should be allowed to dry at temperatures from ambient to a maximum of 160°C

(320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Open windows and use a fan or other active means of ventilation to remove any methanol vapors from the room.

For Pump Spray Application: Dilute 2.5 ounces of AEGIS Antimicrobial per gallon of water. Using pump sprayer, spray entire area 4-6 inches from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and colorfastness of fabrics and carpets by treating and drying a small, concealed area prior to application. When treating coarser substrates, more AEGIS Antimicrobial may be required due to absorption.

For Spray Application: For commercial application equipment, dilute 2.5 ounces of AEGIS Antimicrobial per gallon of water; mix well. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. When treating coarser substrates, more AEGIS Antimicrobial may be required due to absorption. Dry carpet areas and surfaces before re-entry and dry articles before use.

For Dipping/Soaking Application: Use appropriate sized washbasin or tub for dipping/soaking the item you are treating. Use enough AEGIS Antimicrobial solution to completely submerge item. Dilute 2.5 ounces of AEGIS Antimicrobial per gallon of water; mix well. Completely submerge item in solution for 3 minutes. Remove item and dry. Test for staining and color-fastness of fabrics by treating and drying a small, concealed area prior to application. Do not reuse solution after dipping/soaking. The substrate can be dried at room temperatures or at temperatures to a maximum of 160° C (320° F).

For each application, determine optimum application and drying conditions, such as time and temperature before use. If desired, reapply AEGIS Antimicrobial if odor, staining and discoloration due to bacteria, mold or mildew occur.

STORAGE AND DISPOSAL

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

(5lbs. or less)

Storage and Disposal

Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use. Moisture sensitive. Reclose tightly after each use. When stored in original, unopened container at or below 25°C, AEGIS Antimicrobial has a shelf life of 12 months from date of shipment. Do not reuse container. Discard in trash.

(Greater than 5lbs.)

STORAGE: Store in original, tightly closed container in an area inaccessible to children and away from food or feed. Moisture sensitive. Keep tightly closed until ready to use. Reclose tightly after each use. When stored in original, unopened containers at or below 25°C (77°F), AEGIS Antimicrobial has a minimum shelf life of 12 months from date of shipment.

PESTICIDE DISPOSAL: Pesticide is acutely hazardous. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse containers. Do not cut or weld containers. Triple rinse (or equivalent) empty containers. 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. This container will have vapor and/or product residues when emptied. All hazard precautions on label must be observed when handling emptied container.

NOTICE: AEGIS warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in the labeling when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to written instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

AEGIS ENVIRONMENTAL MANAGEMENT, INC. SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.